RETURN DATE: NOVEMBER 30, 2021 : SUPERIOR COURT

MELISSA COWAN, : JUDICIAL DISTRICT OF

ALYSSA GARGIULO, : WATERBURY

BRIANNE MCLOUGHLIN,

LEAH MIRAKHOR, : AT WATERBURY

DILAY NACAR,
AWO OSAFO-ADDO,
NICOLE WASH,
MICHAEL COWAN,
KEITH ZACKOWITZ,
MATTHEW MCLOUGHLIN,
NAVID HAFEZ,
ALPEN NACAR, and

v.

YALE UNIVERSITY

GARY WALSH

NOVEMBER 5, 2021

INTRODUCTION

- 1. This is a civil action for damages stemming from the mass diversion of the opioid, fentanyl, at the Yale University Reproductive Endocrinology and Infertility Clinic ("REI Clinic"), a fertility clinic operated and managed by Yale University, and/or its servants, agents, apparent agents, and/or employees (hereinafter "YALE UNIVERSITY").
- 2. Over a five-month period in 2020, a YALE UNIVERSITY nurse was able to steal the contents of hundreds of vials of fentanyl—a pain medication 50–100 times more potent than morphine—from the opioid stockpiles at the REI Clinic, and replace the medication with saline (water), which was subsequently administered to the clinic's patients.¹
- 3. The result was that dozens, perhaps hundreds, of women underwent the most painful fertility surgeries and procedures offered at the REI Clinic with little or no analgesia.
- 4. The true scale of the mass diversion of fentanyl at YALE UNIVERSITY remains unknown. But a Drug Enforcement Agency inspection and a criminal investigation found that over a five-month period, the diverting nurse adulterated at least 75% of all fentanyl housed at the REI Clinic.
- 5. Plaintiffs are seven of YALE UNIVERSITY's victims.

¹ See United States v. Donna Monticone, No. 3:21 cr31 (JCH), Government's Sentencing Memorandum (DN 22) at *3 (D. Conn. May 18, 2021).

- 6. Each plaintiff was prescribed fentanyl for a particularly invasive procedure performed at the REI Clinic, known as oocyte retrieval.
- 7. But instead of receiving fentanyl to treat their pain, plaintiffs were administered saline.
- 8. For each of these women, the oocyte retrieval, which involves a surgeon maneuvering a thick needle through the vaginal wall, ovarian ligament, ovary, and ovarian follicle to aspirate mature eggs, was excruciating.
- 9. YALE UNIVERSITY providers were alerted to the problem with its supply of fentanyl, the sole analgesic administered to women during oocyte retrievals, through patients' intraoperative screams and postoperative reports of torturous pain.
- 10. But, upon information and belief, YALE UNIVERSITY never investigated these reports. Instead, pain was minimized as "normal" for the invasive procedure, or attributed to the unavailability of an anesthesiologist on Saturdays and Sundays.
- 11. YALE UNIVERSITY takes no responsibility for the hundreds of fentanyl substitution events that took place at the REI Clinic; it blames the single nurse who was able to steal the fentanyl, unabated, for more than twenty weeks.
- 12. But for years, YALE UNIVERSITY recognized the lurking danger of opioid diversion, and the catastrophic injuries posed by healthcare worker opioid substitution.
- 13. YALE UNIVERSITY knew that just one opioid substitution event could result in a multitude of harms—inadequate pain management for patients; the impairment of a healthcare worker, resulting in patient care errors; and the transmission of infectious diseases, like HIV and hepatitis, from an opioid-addicted healthcare worker to patients.
- 14. YALE UNIVERSITY also knew that as one of the largest employers of healthcare workers in Connecticut, an opioid diversion attempt was not a question of if, but when.
- 15. Indeed, the mass diversion of fentanyl at the REI Clinic was not the first or even second time that opioids were diverted by a YALE UNIVERSITY clinician:
 - a. One year earlier, in 2019, a YALE UNIVERSITY resident was arrested on thirty-five counts of narcotic distribution after writing illegal prescriptions for nearly 4,000 oxycodone tablets.²

² See Marisa Peryer, YNHH Resident Arrested; Illegal Narcotics Distribution Suspected (Aug. 14, 2019), https://yaledailynews.com/blog/2019/08/14/ynhh-resident-arrested-illegal-narcotic-distribution-suspected/ (reporting arrest of former Yale New Haven Hospital resident, who was charged with 35 counts of narcotic distribution without a legitimate medical purpose).

- b. Four years earlier, in 2016, a YALE UNIVERISTY nurse was sanctioned by the Connecticut Board of Medical Examiners for using hydromorphone that she stole from Yale-New Haven Hospital.³
- 16. But even after these events, YALE UNIVERSITY failed to implement the most basic, *legally mandated*, steps to prevent against opioid diversion.
- 17. As Yale physicians warned patients to lock their medicine cabinets to minimize the risk of loved-ones accessing opioids, YALE UNIVERSITY failed to secure the very room where it warehoused hundreds of fentanyl vials at the REI Clinic⁴. Unlocked and unsecured, the diverting nurse was able to enter the room containing the opioid stockpiles, unmonitored.⁵
- 18. In fact, YALE UNIVERSITY adopted a business practice that would make another opioid diversion event *more* likely: At the peak of the opioid epidemic, YALE UNIVERSITY implemented a cost-reduction strategy whereby bulk orders of controlled substances, including fentanyl, were placed for delivery and storage on-site at the REI Clinic.
- 19. As part of this unlawful cost-reduction scheme, YALE UNIVERSITY appointed an opioid-addicted nurse—the very nurse who diverted hundreds of vials of fentanyl—to manage the stockpiles of opioids at the REI Clinic, without adequate diversion-prevention or -detection measures in place.
- 20. In adopting this business practice, YALE UNIVERSITY prioritized profits over patient safety.
- 21. Plaintiffs, just seven of YALE UNIVERSITY's victims, seek transparency and justice for themselves and the untold number of women who suffered unimaginable terror and pain at the REI Clinic because of the carelessness and recklessness of YALE UNIVERSITY.

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³ See Kate Farrish, CT Nurses Cited for Stealing Patients' Painkillers, Alcohol Abuse (Apr. 26, 2019), https://www.ctpost.com/local/article/CT-nurses-cited-for-stealing-patients-13798206.php (detailing four-year probation on nurse "who stole the opioid painkiller Hydromorphone for her own use while working as a nurse at Yale New Haven Hospital in 2016").

⁴ See United States v. Donna Monticone, No. 3:21 cr31 (JCH), Government's Sentencing Memorandum (DN 22) at *3 (D. Conn. May 18, 2021).
⁵ Id.

THE PARTIES

THE PLAINTIFFS

22. Plaintiffs are the women and the respective spouses of women who seek damages stemming from the mass diversion of the opioid, fentanyl, at the REI Clinic.

The Patient-Victims of Yale University

- 23. Plaintiffs underwent oocyte retrieval procedures at the REI Clinic in Orange, Connecticut during the five-month period when a REI Clinic nurse admitted to diverting at least 75% of all fentanyl stores at the clinic.
- 24. Prior to undergoing invasive oocyte retrievals, described above, the plaintiffs first completed the following three taxing steps of in vitro fertilization—(1) ovarian suppression, where hormones are administered to downregulate the ovaries for subsequent stimulation; (2) ovarian stimulation, the process of administering a series of injections in the stomachs, buttocks, or upper thighs to initiate an intense stimulation cycle, which is often accompanied by fatigue, nausea and headaches; and (3) ovulation induction, the final step before oocyte retrieval (which must proceed within a specified period immediately thereafter), that is initiated through "trigger shots" containing chorionic gonadotrophin (HCG), Lupron, or both.
- 25. At all times relevant, the plaintiff, MELISSA COWAN was a resident of Naugatuck, Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent an oocyte retrieval at the Orange location of the REI Clinic on or about August 8, 2020. Like plaintiffs DILAY NACAR and NICOLE WALSH, MELISSA COWAN was not offered anesthesiology services (e.g. propofol) for her oocyte retrieval, which proceeded over the weekend, and thus was awake for the duration of the retrieval, and experienced excruciating pain during and after the procedure.
- 26. At all times relevant, the plaintiff, ALYSSA GARGIULO, was a resident of Branford Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent oocyte retrievals at the Orange location of the REI Clinic on or about August 5, 2020 and August 24, 2020. The pain was agonizing during and after both retrievals.
- 27. At all times relevant, the plaintiff, BRIANNE MCLOUGHLIN, was a resident of Cheshire, Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent oocyte retrievals at the Orange location of the REI Clinic on or about May 29, 2020, June 16, 2020, August 13, 2020, and September 4, 2020. Ms. MCLOUGHLIN experienced excruciating pain during and after the oocyte retrievals.
- 28. At all times relevant, the plaintiff, LEAH MIRAKHOR, was a resident of New Haven, Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent oocyte retrievals at the Orange location of the REI Clinic on or about July 1,

- 2020, August 24, 2020, and September 8, 2020. LEAH. MIRAKHOR described excruciating pain during and after the oocyte retrievals.
- 29. At all times relevant, the plaintiff, DILAY NACAR, was a resident of Danbury, Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent oocyte retrievals at the Orange location of the REI Clinic on or about June 8, 2020 and October 4, 2020. Ms. NACAR experienced excruciating pain during and after the oocyte retrievals, but especially on the October 4, 2020 procedure, which was performed without anesthesia.
- 30. At all times relevant, the plaintiff, AWO OSAFO-ADDO, was a resident of Danbury, Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent oocyte retrievals at the Orange location of the REI Clinic on or about June 26, 2020, August 25, 2020, and September 18, 2020, during and after which time she experienced excruciating pain.
- 31. At all times relevant, the plaintiff, NICOLE WALSH, was a resident of Stratford, Connecticut, who contracted with YALE UNIVERSITY to receive fertility services, and underwent oocyte retrievals at the Orange location of the REI Clinic on or about May 30, 2020, August 21, 2020, and September 11, 2020. Ms. WALSH experienced agonizing pain during and after the oocyte retrievals, and experienced excruciating intraoperative pain for the duration of the May 30, 2020 procedure, which was performed without anesthesia.

Plaintiffs—Women Willing to Undergo Taxing and Invasive Procedures for a Chance to Achieve Their Dreams of Parenthood—Were Among a Vulnerable Patient Population

- 32. YALE UNIVERSITY knew plaintiffs were psychologically and emotionally vulnerable by virtue of being infertility patients, and even expressly acknowledged some of the reasons for this vulnerability on its website: "[O]ne partner [may be] more devoted to the process; infertility treatments can stretch on for months and become financially draining; people experiencing infertility [often] end up feeling alone and isolated." ⁶
- 33. Specifically up to one-half of women seeking fertility services describe infertility as the most upsetting experience of their lives. ⁷ Anxiety and fear about the quantity/quality of eggs retrieved and future failures in treatment can create feelings of hopelessness, isolation and

⁶ See Fertility Center Psychological Program, YaleMedicine, https://www.yalemedicine.org/departments/fertility-center-psychological-program (last visited Oct. 27, 2021).

⁷ See Ellen Freeman et al., Psychological Evaluation and Support in Programs of In Vitro Fertilization and Embryo Transfer, https://pubmed.ncbi.nlm.nih.gov/3965315/ (last visited October 29, 2021).

- inadequacy during the process. Indeed, some studies show that infertility causes anguish similar to that accompanying a cancer diagnosis or the loss of a loved one.⁸
- 34. The expense of pursuing fertility treatment also contributed to the special nature of the provider-patient relationship at the REI Clinic. Specifically:
 - a. REI Clinic services are costly. A single IVF cycle—defined as ovarian stimulation, egg retrieval and embryo transfer—can range from \$15,000 to \$30,000.9
 - b. Most insurance plans do not cover in vitro fertilization. 10
 - c. Even in the event that an insurance plan does "cover" the cost of treatment, patients are often responsible for out-of-pocket expenses such as office visits, diagnostic tests/procedures, medication, genetic testing, donor sperm/egg use of storage fees and wages lost from time off work.¹¹

The Defendant: Yale University

- 35. At all times mentioned herein, the defendant, YALE UNIVERSITY, was a specially chartered corporation organized and existing under the laws of the State of Connecticut and operating a hospital in New Haven, Connecticut, called Yale-New Haven Hospital, and the Yale Reproductive Endocrinology Clinic (REI Clinic), supplying physicians and other health care professionals to the same for the treatment of the general public.
- 36. At all times relevant, YALE UNIVERSITY operated and managed the REI Clinic, also known as the Yale Fertility Center ("REI Clinic"), a fertility center that held itself out to the public as providing fertility services, including oocyte suppression, ovarian suppression, ovarian stimulation, and oocyte retrievals.
- 37. At all times relevant YALE UNIVERSITY recruited and employed physicians and health care providers in specialties, including but not limited to gynecology, obstetrics, and reproductive endocrinology, to treat patients at the REI Clinic.
- 38. At all times when REI Clinic services were offered in Orange, Connecticut, there was no pharmacy or pharmaceutical services provided on-site.
- 39. At all times relevant, the REI Clinic was an Outpatient Surgical Facility, as defined by Conn. Gen. Stat. § 19a-493b(a) by the State of Connecticut.

⁸ See Kristin Rooney et al., The Relationship Between Stress and Infertility (March 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6016043/ (last visited October 29, 2021).

⁹ See Marissa Conrad, *How Much Does IVF* Cost, ForbesHealth (Sept. 28, 2021), https://www.forbes.com/health/family/how-much-does-ivf-cost/.

¹⁰ See Nat. Infertility Assoc., *Health Insurance 101*, https://resolve.org/what-are-my-options/insurance-coverage/health-insurance-101/ (last visited Oct. 27, 20201).

See Gabriela Weigel et al., Coverage and Use of Fertility Services in the U.S., KFF (Sept. 15, 2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/.

- 40. At all times relevant, the REI Clinic was a Group Practice, as defined by Conn. Gen. Stat. § 19a-481i(a)(10).
- 41. At all times relevant, the REI Clinic was accredited by the Joint Commission.
- 42. At all times relevant, YALE UNIVERSITY—by or through the REI Clinic, which it operated and managed, and/or its agent(s), apparent(s), and/or employee(s)—made the following representations to induce plaintiffs to contract with YALE UNIVERSITY for their reproductive services:
 - a. that the REI Clinic met and exceeded Best Practices in its provision of all fertility services" 12;
 - b. that "physicians and researchers [at the REI Clinic] use the latest evidence-based fertility [practices]" 13;
 - c. that academic centers, including the REI Clinic, "are more up-to-date on best practices," than the "many places in the country—across the world—that are delivering good care" 14;
 - d. that the REI Clinic uses "a data-driven approach to individualized care" 15;
 - e. that "[u]sing the latest research and fertility science, [the REI Clinic's] goal is to maximize [its] patient's chances of successful pregnancy in the shortest possible time and with the *utmost attention to the wellbeing of our patients* and their future generations" ¹⁶;
 - f. that "[a]ll treatments" that Yale REI Clinic "offer[s] are vetted by solid data" 17;
 - g. that the REI Clinic "prioritize[s] patient safety and maximize[s] patient success" 18;
 - h. that "[t]ogether with our highly trained and experienced nurses and laboratory staff, we strive to make the fertility treatment a stress-free experience for our patients." 19
- 43. At all times relevant, YALE UNIVERSITY—by or through the REI Clinic, which it operated and managed—represented in promotional/informational videos that oocyte retrievals would take approximately 30 minutes and would be conducted with "a combination of medications to keep you comfortable."

¹² Carrie Macmillan, Fertile Ground? The Truth Behind the (IVF) Headlines, YaleMedicine (Apr. 12, 2018), https://www.yalemedicine.org/news/ivf-truth.

¹³ *Id*.

¹⁴ Id. (quoting Lubna Pal, MBBS, Interim Section Chief of REI at Yale Medicine)

¹⁵ Id. (quoting Lubna Pal, MBBS, Interim Section Chief of REI at Yale Medicine)

¹⁶ YaleMedicine, Female Infertility, https://www.yalemedicine.org/conditions/infertility (last visited Oct. 27, 2021) (emphasis added).

¹⁷ *Id*.

¹⁸ *Id.* (quoting Lubna Pal, MBBS).

¹⁹ YaleMedicine, In Vitro Fertilization (IVF) Fact Sheet, https://www.yalemedicine.org/conditions/ivf (last visited Oct. 27, 2021).

- 44. At all times relevant, to complete oocyte retrievals, YALE UNIVERSITY providers ordered the administration of the potent opioid, fentanyl, to each and every woman undergoing the invasive procedure at the clinic.
- 45. At all times relevant, YALE UNIVERSITY—by and through the REI Clinic—additionally stated that a patient "may experience minor discomfort but should be recovered in a couple of hours."
- 46. At all times relevant, YALE UNIVERSITY—by or through the REI Clinic, which it operated and managed—billed plaintiffs in return for the provision of fertility services to plaintiffs.

Agents, Apparent Agents, and Employees of Yale University

- 47. At all times relevant, Donna Monticone, RN, was an agent, apparent agent, and/or employee of the defendant, YALE UNIVERSITY, who was certified as a registered nurse by the Connecticut Department of Public Health, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 48. At all times relevant, Jenna Barolli, RN, was an agent, apparent agent, and/or employee of the defendant, YALE UNIVERSITY, who was certified as a registered nurse by the Connecticut Department of Public Health, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 49. At all times relevant, Maureen Pothier, RN, was an agent, apparent agent, and/or employee of the defendant, YALE UNIVERSITY, who was certified as a registered nurse by the Connecticut Department of Public Health, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 50. At all times mentioned herein, Trevor Banack, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 51. At all times mentioned herein, Trevor Banack, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 52. At all times mentioned herein, Jill Berlin, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 53. At all times mentioned herein, Jill Berlin, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 54. At all times mentioned herein, Marcelle Blessing, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 55. At all times mentioned herein, Marcelle Blessing, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.

- 56. At all times mentioned herein, Robert Chow, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 57. At all times mentioned herein, Robert Chow, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 58. At all times mentioned herein, Jeremy Dennis, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 59. At all times mentioned herein, Jeremy Dennis, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 60. At all times mentioned herein, Jinlei Li, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 61. At all times mentioned herein, Jinlei Li, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 62. At all times mentioned herein, Alena Rady, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 63. At all times mentioned herein, Alena Rady, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 64. At all times mentioned herein, Jill Zafar, MD, was certified by the appropriate American board as a specialist in anesthesiology, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 65. At all times mentioned herein, Sandra Carson, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 66. At all times mentioned herein, Sandra Carson, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 67. At all times mentioned herein, Stephen Collins, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 68. At all times mentioned herein, Stephen Collins, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 69. At all times mentioned herein, Valerie Flores, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.

- 70. At all times mentioned herein, Valerie Flores, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 71. At all times mentioned herein, Amanda Kallen, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 72. At all times mentioned herein, Amanda Kallen, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 73. At all times mentioned herein, Pinar Kodaman, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 74. At all times mentioned herein, Pinar Kodaman, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 75. At all times mentioned herein, Alexander Kotlyar, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 76. At all times mentioned herein, Alexander Kotlyar, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 77. At all times mentioned herein, Amir Mor, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 78. At all times mentioned herein, Amir Mor, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 79. At all times mentioned herein, Lubna Pal, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.
- 80. At all times mentioned herein, Lubna Pal, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 81. At all times mentioned herein, Pasquale Patrizio, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 82. At all times mentioned herein, Pasquale Patrizio, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 83. At all times mentioned herein, Samantha Simpson, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held herself out as a specialist in that field.

- 84. At all times mentioned herein, Samantha Simpson, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 85. At all times mentioned herein, Reshef Tal, MD, was certified by the appropriate American board as a specialist in reproductive endocrinology/infertility, was trained and experienced in that medical specialty, and/or held himself out as a specialist in that field.
- 86. At all times mentioned herein, Reshef Tal, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.
- 87. At all times mentioned herein, Jill Zafar, MD, was a servant, agent, apparent agent, and/or employee of the defendant YALE UNIVERSITY.

YALE UNIVERSITY KNEW OR SHOULD HAVE KNOWN ABOUT THE HIGH LIKELIHOOD OF OPIOID DIVERSION, PARTICULARLY AT THE REI CLINIC, AND THE SEVERE HARMS THAT COULD RESULT

<u>Yale University Knew or Should Have Known about High Likelihood of an Opioid</u> <u>Diversion Attempt by One of Its Healthcare Workers</u>

Opioid Diversion at Healthcare Institutions is a Common Problem with a Common Origin: The Modern Opioid Epidemic

Opioid Dependence and Addiction

- 88. Fentanyl is an invaluable medication for its potent pain-blocking power. Indeed, its use is so important for the treatment and prevention of pain, that the World Health Organization has recognized fentanyl among its list of "Essential Medications"—the "minimum medicine needs for a basic health-care system."²⁰
- 89. But because fentanyl activates powerful rewards centers in the brain, causing the release of endorphins—the brain's feel-good neurotransmitters—it is also subject to abuse and dependence.
- 90. When opioids are used repeatedly over time, the body slows its natural production of endorphins, leading to a diminished sense of euphoria with administration, a process known as tolerance. Individuals who develop tolerance require larger doses of opioids to produce the same levels of euphoria. They also develop symptoms of withdraw without continued use.
- 91. Today, millions of Americans are dependent or addicted to opioids. Over a half million Americans have died²¹ from opioid overdoses since 1999.

²⁰ WHO Model List of Essential Medicines, March 2017 20th Ed. at 3.

²¹ Opioids kill by decreasing the sensitivity of the body to carbon dioxide and interfering with the regions of the brain that control breathing, causing the cessation of breathing.

92. Fentanyl's high risk of abuse and dependence accounts for its regulation as a Schedule II controlled substance—a classification reserved for treatments that pose the *highest* risk of abuse and dependence. 21 U.S.C. 812(b)(2).

Opioid Diversion by Healthcare Workers Is Common

- 93. Healthcare workers are not immune from opioid tolerance, dependence, and abuse. In fact, healthcare workers, who frequently have access to controlled substances, are at *higher* risk for the misuse of prescription drugs, including opioids.
- 94. The act of stealing or redirecting a controlled substance from a legal source, such as a hospital or clinic, to an illicit market or illicit use, is known as "diversion." Healthcare workers who are opioid-addicted or -dependent sometimes resort to stealing opioids, including fentanyl, to support their addiction or dependence.
- 95. The Centers for Disease Control (CDC) has designated a specific type of diversion—substitution—as the "worst" kind of drug diversion because of the harm that it poses to the patients of healthcare workers.
- 96. Substitution occurs when a healthcare worker diverts medication from a syringe, vial or other container and replaces medication with a similarly appearing substance. Typically the substitution of fentanyl occurs with the replacement of saline or water, both of which are visually indistinguishable.
- 97. Opioid diversion by healthcare providers has been documented for decades, even before opioid abuse reached epidemic proportions in the 1990s. The current opioid diversion crisis facing the healthcare industry reflects the history of opioid marketing and regulation in the United States, in what has been termed the "Three Waves" of the modern opioid epidemic.
- 98. In the "First Wave" of the modern opioid epidemic began in the early 1990s, when pharmaceutical companies—such as Purdue Pharma—began peddling opioids as a non-addictive treatment for pain. As prescriptions climbed, so did opioid deaths, in what became known as the "First Wave" of the modern opioid epidemic.
- 99. In the mid-2000s, in what is characterized "Second Wave" of the opioid epidemic, physicians, scrutinized for indiscriminate opioid prescribing practices, adopted more stringent prescribing practices. Opioid overdoses surged as individuals hooked on prescription opioids turned to a cheap and readily available substitute—heroin.
- 100. Today, America is in the midst of the "Third Wave" of the opioid epidemic, which began when powerful synthetic opioids—particularly fentanyl—entered illicit markets from both legal and illicit sources. In 2017, the opioid death rate had climbed to such dire levels that the Department of Health and Human Services declared the opioid epidemic a "public health crisis." This declaration coincided with a grave milestone: For the first time in history, an American was more likely to die from an accidental opioid overdose than from a motor vehicle collision.
- 101. During the second and third waves of the opioid epidemic, opioid diversion by healthcare workers became increasingly common as sources of legally prescribed opioids evaporated. For example, in 2014, the hospital manager of controlled substance surveillance at a

- university medical center reported, "I was catching at least one health care provider every month stealing medication." ²²
- 102. Studies suggest that even this hospital manager's account underrepresents the scope of the problem: One study identified more than 1 discrepancy involving a controlled substances—indicative of diversion—for every Medicare patient treated at a healthcare facility.²³

Yale University, One of the Largest Employer of Healthcare Workers in the State, Knew or Should Have Known That It Was a Matter of Time Before One of Its Healthcare Workers Would Attempt to Divert Opioids

- 103. While horrific, the mass substitution of fentanyl at the REI Clinic was foreseeable.
- 104. It is inevitable that unless strict measures are implemented, diversion will take place in large healthcare institutions, including YALE UNIVERSITY.
- 105. YALE UNIVERSITY knew or should have known that it likely employed dozens of healthcare workers who were dependent or addicted to controlled substances, particularly opioids. Application of conservative prevalence rates for addiction and dependence suggests that by 2017, Yale New Haven Health Services Corporation, the parent company of YALE UNIVERSITY and the largest employer of healthcare workers in the State of Connecticut, likely employed more than 600 medical staff who abuse drugs and dozens of nurses who practice while impaired.²⁴
- 106. By June 2017, the opioid crisis had reached epidemic proportions across the state. To address this epidemic, on June 14, 2017, YALE UNIVERSITY faculty hosted a media

²² Keith H. Berge & William L. Lanier, Editorial, Bloodstream Infection Outbreaks Related to Opioid-Diverting Health Care Workers: A Cost-Benefit Analysis of Prevention and Detection Programs, 89 Mayo Clin. Proc. 866, 867 (2014).

²³ Chukwuma Anyanwu & Oliver Egwim, *The Prevalence and Determinants of Controlled Substance Discrepancies in a Level I Trauma Hospital*, 9 Am. Health Drug Benefits 128, 132 (2016).

²⁴ See YaleNewHavenHealth, Facts and Figures, https://www.ynhhs.org/about/corporate-overview/system-statistics.aspx (last visited Apr. 20, 2021) (noting that as the largest employer in Connecticut, Yale employs over 26,000 employees including more than 6,600 medical staff) and The Joint Commission, Drug Diversion and Impaired Health Care Workers, 48 Quick Safety 1 (2019), available at https://www.jointcommission.org/media/tjc/newsletters/quick_safety_drug_diversion_final2pdf.pdf (noting that The American Nurses Association (ANA) has estimated that one in 10 health care workers abuse drugs); see also Hazel Y. Tanga, Nurse Drug Diversion and Nursing Leaders' Responsibilities: Legal, Regulatory, Ethical, Humanistic, and Practical Considerations, 13 JONA's Healthcare Law, Ethics, and Regulation 11, 16 (2011) (citing ANA estimates that 6% to 8% of nurses are currently practicing while impaired).

- roundtable about the opioid crisis in collaboration with CORE, "a statewide initiative to address the opioid crisis and stem the rising tide of overdose deaths." ²⁵
- 107. About one week later after this media roundtable, twenty overdoses and three deaths were recorded at Yale-New Haven Hospital after a single batch of fentanyl-laced powder was consumed by dozens in the vicinity of the New Haven Green. An article detailing the harrowing event, which appeared in the Winter edition of Yale Medicine, noted that "deaths from fentanyl" were increasing in the state—disproportionately in New Haven: "In the first three months of 2016, fentanyl was involved in 83 out of 119 fatal overdoses, with New Haven leading the state with 24 deaths."
- 108. Indeed, the REI Diversion event took place at a time when opioid abuse were approaching record highs in Connecticut. For example, while Connecticut hospitals reported only fourteen fentanyl-related deaths statewide in 2012, just seven years later, statewide deaths surged to nearly 1,000. In fact, by 2020, fentanyl was responsible for 82% of all unintentional drug overdose deaths statewide, a 7,000% increase from 2012.²⁸
- 109. Although horrific, the figures actually underrepresented the severity of the epidemic in YALE UNIVERSITY's own backyard: By July 2020, the rate of fentanyl overdose-related deaths in New Haven County were double and six-times that of bordering Fairfield and Middlesex counties, respectively.²⁹
- 110. In fact, years before the mass diversion of fentanyl at the REI Clinic, YALE UNIVERSITY had already witnessed drug diversion by healthcare workers at its own facilities—the 2016 diversion of hydromorphone by a nurse at Yale-New Haven

²⁵ Denise Meyer, Yale Faculty Host Media Roundtable About the Opioid Crisis, (June 15, 2017), https://ysph.yale.edu/news-article/yale-faculty-host-media-roundtable-about-the-opioid-crisis/.

²⁶ Sarah Faulkner, Yale Sch. Medicine, An Opioid Crisis in the City and a Bad Night in the Emergency Room, https://medicine.yale.edu/news/yale-medicine-magazine/an-opioid-crisis-in-the-city-and-a/ (last visited Oct. 27, 2021).

²⁷ *Id*.

²⁸ See id. ("In 2012, fentanyl was involved in 14 fatal overdoses."); Heather Clinton, Conn. Dept. Pub. Health, *Drug Overdose Deaths in Connecticut Data Dashboard*, 2015 to 2021, https://public.tableau.com/app/profile/heather.clinton/viz/SUDORS Dashboard final2/Overdose Dashboard (last visited Oct. 27, 2021) (hereinafter Clinton, *Drug Overdose Dashboard*) (detailing, on county-level, drug overdose death data in Connecticut between 2015 and 2021).

²⁹ See Clinton, Drug Overdose Dashboard (comparing fentanyl-related overdoses across New Haven, Fairfield, and Middlesex Counties in July 2020).

- Hospital³⁰ and the 2019 diversion of nearly 4,000 oxycodone tablets by a Yale-New Haven Hospital Emergency Medicine resident³¹.
- 111. All healthcare workers are potentially at risk for diverting controlled substances. But known risk factors for opioid diversion highlighted that a diversion event was particularly likely at the REI Clinic.
- 112. Specifically, nurses who practice in surgical areas are at high risk for diverting opioids.³² The drug that the REI Clinic nurse diverted, fentanyl, is the most commonly diverted opioid, which itself, is the most commonly diverted drug class³³.

<u>Yale University Knew or Should Have Known that Opioid Diversion Posed a Serious Threat to Patient Safety: Inadequate Analgesia, Infectious Disease Outbreaks, and Impaired Healthcare Workers</u>

- 113. YALE UNIVERSITY knew or should have known that diversion prevention and detection interventions were necessary because of the severity of harm associated with opioid substitution, a class of diversion.
- 114. The first harm of opioid substitution is the excruciating pain that patients suffer when an opioid is replaced with another substance.
- 115. Years and even decades before the mass diversion event at REI Clinic, accounts of AIDS patients not receiving medications for excruciating pain while in palliative care,³⁴ and

³⁰ See Kate Farrish, CT Nurses Cited for Stealing Patients' Painkillers, Alcohol Abuse (Apr. 26, 2019), https://www.ctpost.com/local/article/CT-nurses-cited-for-stealing-patients-13798206.php (detailing four-year probation on nurse "who stole the opioid painkiller Hydromorphone for her own use while working as a nurse at Yale New Haven Hospital in 2016").

³¹ See Marisa Peryer, YNHH Resident Arrested; Illegal Narcotics Distribution Suspected (Aug. 14, 2019), https://yaledailynews.com/blog/2019/08/14/ynhh-resident-arrested-illegal-narcotic-distribution-suspected/ (reporting arrest of former Yale New Haven Hospital resident, who was charged with 35 counts of narcotic distribution without a legitimate medical purpose).

³² See Carlos A. Pellegrini, Bulletin: Joint Commission Focuses on Strategies to Detect, Prevent Drug Diversion, (June 1, 2019) https://bulletin.facs.org/2019/06/joint-commission-focuses-on-strategies-to-detect-prevent-drug-diversion/ (describing "some of the most high-risk care settings" for drug diversion as including "surgical suites, surgical centers, anesthesia and procedural areas").

³³ The Joint Commission, *Drug Diversion and Impaired Health Care* Workers, 48 Quick Safety 1 (2019), available at https://www.jointcommission.org/media/tjc/newsletters/quick_safety_drug_diversion_final2pdf.pdf

³⁴ See Keith H. Berge, MD et al., Diversion of Drugs within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention, 87 Mayo Clin. Proc. 674, 676 (2012) (detailing case report of a procedural sedation nurse assigned to administer opioids and sedatives to patients during colonoscopy substituting fentanyl for saline,

- patients experiencing torturous, untreated, pain during invasive procedures and surgeries, such as colonoscopies³⁵ and kidney procedures,³⁶ were published in widely circulated peer-reviewed medical journals.
- 116. At the REI Clinic, fentanyl was the only analgesic ordered for pain relief during oocyte retrieval surgeries. Accordingly, in cases where fentanyl was substituted with saline, patients—including the plaintiffs—were left to endure excruciating pain.
- 117. Plaintiffs' reports of excruciating pain were either dismissed by healthcare providers as "normal" for oocyte retrievals, or in cases where an anesthesiologist was not present, blamed on the absence of anesthesia.
- 118. A second chief harm of opioid substitution is potential exposure of patients to bloodborne infectious disease, such as HIV and hepatitis. The medical literature is replete with case reports of dozens, hundreds, or even thousands of patients exposed to pathogens because of the nonsterile practices of a substituting healthcare worker:
 - a. A single healthcare worker can potentially expose *thousands* of patients to bloodborne pathogens. In fact, the CDC reported that between 2008 and 2019, 28,989 individuals were exposed to hepatitis C infection from the substitution of controlled substances by just *four* healthcare workers³⁷;
 - b. The traveling radiographer who infected 32 and exposed 1700 to hepatitis at a New Hampshire hospital³⁸;
 - c. The Wisconsin nurse who infected six and killed one with a deadly bacteria, *Serratia marcescens*, after substituting morphine from patient-controlled analgesia syringes in 2014³⁹.

administering saline to her patients, and diverting the fentanyl for her own use) [hereinafter Berge, *Diversion of Drugs*].

³⁵ See James A. Inciardi et al., The Diversion of Prescription Drugs by Health Care Workers in Cincinnati, Ohio, 41 Substance Use & Misuse 255, 259 (2006) (detailing how an Ohio hospice nurse substituted vials of opioids prescribed for palliative care to AIDS patients for tap water, using the opioids to support her drug habit).

³⁶ See Berge, Diversion of Drugs, at 676 (documenting diversion of fentanyl by Mayo Clinic sedation nurse who instructed the patient that he would have to "man up" and tolerate some pain during kidney procedure because he could not be given much pain medication).

³⁷ See CDC, Healthcare-Associated Hepatitis B and C Outbreaks > 2 Reported to the CDC 2008-2019, https://www.cdc.gov/hepatitis/Outbreaks/PDFs/HealthcareInvestigationTable.pdf (last updated May 11, 2020).

³⁸ See id.

³⁹ See Leah M. Schuppener et al., Serratia Marcescens *Bacteremia: Nosocomial Cluster Following Narcotic Diversion*, 38 Infect Control Hosp Epidemiol 1027-31 (2017).

- 119. Third, healthcare workers who self-administer substituted opioids while caring for patients potentially expose patients to medical errors and inaccurate documentation of care.
- 120. At least one plaintiff noted on the day of an oocyte retrieval that the nurse who subsequently admitted to diverting fentanyl from the REI Clinic appeared impaired and acted inappropriately; this plaintiff did not file a report because the retrieval had to occur that day she feared the repercussions of filing a complaint.

YALE UNIVERSITY FAILED TO IMPLEMENT DIVERSION PREVENTION AND DETECTION MEASURES AT EVERY STAGE OF THE MEDICATION USE PROCESS, DESPITE FEDERAL LAW, STATE LAW, BEST PRACTICES, AND YALE UNIVERSITY POLICIES REQUIRING OTHERWISE

- 121. YALE UNIVERSITY was required by federal and state statutes, regulations, and guidance to prevent opioid diversion at *every* stage of the medication use process: from procurement, storage, prescribing, dispensing, administration through disposal.
- 122. At all times relevant, the Drug Enforcement Administration additionally required YALE UNIVERSITY to adhere to the best available practices for patient safety and drug security, regardless of whether those practices were explicitly spelled out in published regulations.

Diversion Prevention Failures

- 123. Yet, during one or more stages of the medication use process, YALE UNIVERSITY failed to identify, adopt, implement and/or enforce the following opioid diversion prevention measures at the REI Clinic, as set forth below:
 - a. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - b. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to *different* healthcare workers;
 - c. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. § 1304.11; 21 C.F.R. § 1301.52(e)(1);
 - d. improperly allowed flexible ordering of fentanyl with large dose ranges;
 - e. improperly stored fentanyl at the REI Clinic in a room that was not always locked, and that the diverting nurse was able to access "without swiping her card," in violation of:
 - i. Medicare Conditions of Participation requiring all scheduled drugs, including fentanyl to be stored in a locked secured are that is accessible only to

- authorized personnel, *see*, *e.g.*, 42 C.F.R. § 482.25[b][2][i]); Interpretive Guidelines 42 C.F.R. §482.25[b][2][iii];
- ii. Connecticut Regulations requiring that stock totals for Schedule II drugs, such as fentanyl, that exceed 15 controlled substance units be stored in an approved safe in a securely safeguarded location, see, e.g., Regs. Conn. St. Agencies § 21a-262-6;
- iii. Connecticut Regulations forbidding controlled substance stocks from being "left unsecured or unattended in an examining room, treatment room, . . . or in any other location accessible to nonauthorized persons," *id.*;
- iv. Best practices requiring electronic monitoring of storage sites with camera surveillance of areas not secured by electronic access;
- v. YALE UNIVERSITY's own policies governing the storage of Schedule II controlled substances, *see* Yale Env. Health & Safety, Safety Guidelines: Proper Storage of Controlled Substances.
- f. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent, *see*, *e.g.*, 21 U.S.C. § 827(b); 21 C.F.R. §§ 1301.52(e)(1), 1304.04(a), 1305.03; Conn. Gen. Stat. § 21a-254(f);
- g. failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;
- h. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- i. failed to create, implement, enforce, and/or regularly review or update policies and procedures to prevent the diversion of controlled substances, as required by Medicare Conditions of Participation, *see*, *e.g.*, Interpretive Guidelines 42 C.F.R. § 482.25;
- j. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- k. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- 1. failed to educate employees/agents on diversion, including the *mandatory* obligation of healthcare workers to report suspected diversion.

Diversion Detection Failures

- 124. YALE UNIVERSITY, at all times relevant, additionally failed to develop, implement, or enforce policies and procedures necessary to the timely detection of fentanyl diversion.
- 125. YALE UNIVERSITY, at all times relevant, failed to complete mandated supervised inventory checks of stored fentanyl, as evidenced by its nurse's ability to remove 175 vials

- of fentanyl from REI stock undetected, and the nurse's ability to refill vials of extracted fentanyl with sterile saline at home.⁴⁰
- 126. YALE UNIVERSITY, at all times relevant, failed to follow best practices for the inspection of stored inventory for tampering, as evidenced by the FDA's identification of *multiple* puncture marks in the septa of single-dose fentanyl vials that were confiscated from the REI Clinic.⁴¹
- 127. YALE UNIVERSITY providers, at all times relevant, either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion—despite Medicare Conditions of Participation requirements that mandate healthcare institutions to "promptly investigate and resolve patient complaints and grievance," and provide a safe environment for patients that is "free from the threat or abuse of harm." See, e.g., 42 C.F.R. §§ 482.13(a)(2), 482.13(c)(2).
- 128. YALE UNIVERSITY, at all times relevant, knew or should have known that the REI Clinic nurse was practicing while impaired and likely to be diverting fentanyl. But, upon information and belief, reports from patients that the REI nurse appeared to be practicing while impaired were not investigated or acted upon. The absence of such reports in the presence of clear signs of diversion suggest that employees/agents of YALE UNIVERSITY were unaware that they were required by DEA regulations and Medicare Conditions of Participation to report suspected diversion. See, e.g., 21 C.F.R. § 1301.91; 42 C.F.R. § 482.25(b)(7).
- 129. YALE UNIVERSITY, at all times relevant, further failed to identify, adopt, implement and/or enforce diversion detection measures that would have allowed for timely recognition of fentanyl diversion at the REI Clinic as set forth below:
 - a. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects, as required by federal regulations, *see*, *e.g.*, 42 C.F.R. § 482.25[b][1];
 - b. failed to conduct audits of opioid administered in surgical and procedure areas a the end of every shift;
 - c. failed to conduct regular inspection of fentanyl inventory for tampering;
 - d. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;

⁴⁰ See United States v. Donna Monticone, No. 3:21 cr31 (JCH), Government's Sentencing Memorandum (DN 22) at *3 (D. Conn. May 18, 2021).

⁴¹ See id.

- e. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations, *see*, *e.g.*, 21 C.F.R. § 1304.04 *et seq.*; 42 C.F.R. § 482.24[c][2];
- f. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted;
- g. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, within the Yale-New Haven Health System, and to investigate reports of possible diversion;
- h. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration.

YALE UNIVERSITY'S BUSINESS DECISION TO PURSUE BULK ORDERING OF FENTANYL UNLAWFULLY PRIORITIZED PROFITABILITY OVER PATIENT SAFETY AND MADE DIVERSION MORE LIKELY

- 130. By 2018, Yale publicly boasted about the "myriad [of] ways" that Yale faculty have confronted the opioid crisis, including the "Yale-developed plan to curb opioid overdose crisis."
- 131. Yet, just two years later, YALE UNIVERSITY made a cost-saving business-decision that *eliminated* protections against opioid diversion and made diversion *more* likely.

<u>Despite the Risk of Opioid Diversion, Yale University Abandoned Pharmacy Oversight of Controlled Substances for Cost-Saving Bulk Ordering at the REI Clinic.</u>

- 132. At some time in early 2020, the REI Clinic was located in the Long Wharf section of New Haven, approximately two miles from Yale-New Haven Hospital. During this time, upon information and belief, controlled substances were ordered from a pharmacy immediately before a scheduled surgery or invasive procedure.
- 133. Within the first two months of 2020, the REI Clinic was relocated about seven miles from Yale-New Haven Hospital to the Yale West Campus in Orange, Connecticut. At the time of REI Clinic's relocation, the Yale West Campus did not house *any* clinical practice: The REI Clinic was its first.⁴³

⁴² Ziba Kashef, *Yale-Developed Plan to Curb Opioid Overdose Crisis Helps State, Nation*, YaleNews, (Apr. 30, 2018), https://news.yale.edu/2018/04/30/yale-developed-plan-curb-opioid-overdose-crisis-helps-state-nation.

⁴³ Jon Atherton, *Yale Medicine Reproductive Endocrinology and Infertility to Relocate to West Campus* (Dec. 13, 2018), https://westcampus.yale.edu/news/yale-medicine-reproductive-endocrinology-infertility-relocate-west-campus?refresh=2.

- 134. At or around the time that the REI Clinic relocated to the Yale West Campus, YALE UNIVERSITY made the business decision to pursue "bulk ordering" of controlled substances, whereby mass quantities of fentanyl were ordered directly from manufacturers distributors (instead of pharmacies) for on-site storage.⁴⁴
- 135. Under the new bulk ordering procedure, YALE UNIVERSITY designated a nurse—not a pharmacist—with ordering mass quantities of fentanyl for the entire REI Clinic directly from controlled substance manufacturers and distributors.
- 136. Specifically, the nurse who subsequently admitted to diverting fentanyl from the REI Clinic was appointed by YALE UNIVERSITY to serve as the Alternate Coordinator for the clinic's Controlled Substance Ordering System (CSOS),⁴⁵ whereby large quantities of fentanyl were ordered using the DEA registration number of a physician or the institution.
- 137. Upon information and belief, YALE UNIVERSITY's business decision to pursue "bulk ordering" of fentanyl was made in whole or in part to reduce costs or increase the profitability of the REI Clinic.

<u>Yale University's Bulk Ordering of Fentanyl Eliminated Critical, Mandated, Diversion Protections and Left Hundreds of Fentanyl Vials Unsecured.</u>

- 138. Upon information and belief, YALE UNIVERSITY's business decision to pursue "bulk ordering" greatly reduced or entirely eliminated pharmacy supervision and control over the procurement, storage, dispensing, and destruction of controlled substances, such as fentanyl.
- 139. Under the bulk ordering procedure, mass quantities of fentanyl were stored on-site at the REI Clinic.
- 140. By minimizing or eliminating pharmacy oversight of fentanyl procurement, storage, dispensing, administration, and disposal, YALE UNIVERSITY increased the likelihood of widespread diversion.
- 141. Further exacerbating the risk of harm created by YALE UNIVERSITY's bulk ordering of fentanyl, the REI Clinic lacked basic protections against the diversion of fentanyl, many of which were required by federal *and* state law, as detailed herein.
- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of MELISSA COWAN for the same or similar condition, which included one or more oocyte retrievals performed in 2020.

⁴⁴ See United States v. Donna Monticone, No. 3:21 cr31 (JCH), Government's Sentencing Memorandum (DN 22) at *3 (D. Conn. May 18, 2021).

⁴⁵ See id.

- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, MELISSA COWAN suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.
- 144. The said injuries suffered by MELISSA COWAN, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein:
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances;
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;
 - f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to *different* healthcare workers;
 - h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, *see*, *e.g.*, 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
 - i. allowed inappropriate flexible ordering of fentanyl;
 - failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance;
 - k. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
 - failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;

- m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the *mandatory* obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- s. either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects:
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;
- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;
- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted;
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates, including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;
- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;

- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations;
- jj. failed to offer and provide appropriate anesthesiology services and pain management to plaintiff, who underwent an oocyte retrieval on a Saturday or Sunday.
- 145. On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit A.

COUNT TWO:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-145. Paragraphs 1-145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FIVE (145), respectively, of this COUNT TWO.
- 146. At all times mentioned herein, the plaintiff, MICHAEL COWAN, was the husband of MELISSA COWAN.
- 147. As a result of the aforesaid injuries of plaintiff MELISSA COWAN, MICHAEL COWAN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT THREE:

- 1-144. Paragraphs 1 through 143, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT THREE.
- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11;
 - c. 21 C.F.R. § 1301.52(e);

- d. 21 C.F.R. § 1301.91;
- e. 21 C.F.R. §1304.04;
- f. 21 C.F.R. § 1305.03;
- g. 42 C.F.R. § 482.13;
- h. 42 C.F.R. § 482.24;
- i. 42 C.F.R. § 482.25;
- j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");
- k. Conn. Gen. Stat. § 21a-254;
- 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT FOUR:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-146. Paragraphs 1-146 of COUNT THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-SIX (146) respectively, of this COUNT FOUR.
- 147. At all times mentioned herein, the plaintiff, MICHAEL COWAN, was the husband of MELISSA COWAN.
- 148. As a result of the aforesaid injuries of plaintiff MELISSA COWAN, MICHAEL COWAN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FIVE:

- 1-143. Paragraphs 1-142, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FIVE.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.
- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.
- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.

- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its performance of oocyte retrieval procedures on weekends or holidays without anesthesiology services increased the likelihood that diversion would take place at those times, result in inadequate pain management, and pose an unreasonable and egregious risk of physical injury to its patients.
- 150. Upon information and belief, YALE UNIVERSITY made the business decision to not offer anesthesiology services for oocyte retrievals performed on weekends or holidays to reduce costs and/or maximize profits.
- 151. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of offering anesthesiology services for oocyte retrievals only on weekdays and non-holidays was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 152-59. Paragraphs 144-151 of COUNT FOURTEEN are hereby incorporated and realleged as paragraphs ONE HUNDRED FIFTY-TWO through ONE HUNDRED FIFTY-NINE (159) respectively, of this COUNT FIVE.
- 160. YALE UNIVERSITY's breach of contract, as addressed in COUNT FOURTEEN and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 161. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 162. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 163. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT SIX:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-163. Paragraphs 1-163 of COUNT FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED SIXTY-THREE (163) respectively, of this COUNT SIX.
- 164. At all times mentioned herein, the plaintiff, MICHAEL COWAN, was the husband of MELISSA COWAN.
- 165. As a result of the aforesaid injuries of plaintiff MELISSA COWAN, MICHAEL COWAN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SEVEN:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-151. Paragraphs 1-151 of COUNT FIFTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-ONE (151) respectively, of this COUNT SEVEN.
- 152. YALE UNIVERSITY's breach of contract, as alleged in COUNT FIFTEEN and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 153. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 154. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 155. As a result of YALE UNIVERSITY's violation of CUTPA, MICHAEL COWAN suffered harm, including mental anguish and/or money damages.

COUNT EIGHT:

- 1-143. Paragraphs 1-142, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT EIGHT.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.

- 146. With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY;
 - c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.
- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.
- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:
 - a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
 - b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
 - c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.

d. YALE UNIVERSITY prioritized and effectuated its own interests—including its interests in cost-reduction and profit maximization—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it failed to provide anesthesiology services to patients undergoing oocyte retrievals on Saturdays, Sundays, and holidays.

COUNT NINE:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-148. Paragraphs 1-148 of COUNT EIGHT are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-EIGHT (148) respectively, of this COUNT NINE.
- 149. At all times mentioned herein, the plaintiff, MICHAEL COWAN, was the husband of MELISSA COWAN.
- 150. As a result of the aforesaid injuries of plaintiff MELISSA COWAN, MICHAEL COWAN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT TEN:

- 1-143. Paragraphs 1-142, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT TEN.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.
- 146. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.
- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks

- and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 150. On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.
- 153. As a further result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for each and every oocyte retrieval, plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 154. As a further result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for each and every oocyte retrieval, the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT ELEVEN:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-154. Paragraphs 1-154, of COUNT TEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FOUR (154) respectively, of this COUNT ELEVEN.
- 155. At all times mentioned herein, the plaintiff, MICHAEL COWAN, was the husband of MELISSA COWAN.
- 156. As a result of the aforesaid injuries of plaintiff MELISSA COWAN, MICHAEL COWAN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT TWELVE: MELISSA COWAN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT TWELVE.
- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.
- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;

- c. mental and emotional distress;
- d. loss of quality of life;
- e. impaired future earning capacity;
- f. psychological, physiological and neurological sequelae.
- 154. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT THIRTEEN: MICHAEL COWAN v. YALE UNIVERSITY

- 1-155. Paragraphs 1-155 of COUNT TWELVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FIVE (155) respectively, of this COUNT THIRTEEN.
- 156. At all times mentioned herein, the plaintiff, MICHAEL COWAN, was the husband of MELISSA COWAN.
- 157. As a result of the aforesaid injuries of plaintiff MELISSA COWAN, MICHAEL COWAN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FOURTEEN: MELISSA COWAN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FOURTEEN.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.

- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT FIFTEEN:

MICHAEL COWAN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FIFTEEN.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff, MICHAEL COWAN, under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff, MICHAEL COWAN, agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. MICHAEL COWAN performed the terms and conditions required of him under his contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, MICHAEL COWAN, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened his objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff, MICHAEL COWAN, suffered harm, including mental anguish and/or money damages.

COUNT SIXTEEN:

ALYSSA GARGIULO v. YALE UNIVERSITY

- 1-141. Paragraphs 1-141 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-ONE (141) respectively, of this COUNT SIXTEEN.
- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of ALYSSA GARGIULO for the same or similar condition, which included one or more oocyte retrievals performed in 2020.
- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, ALYSSA GARGIULO suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity
 - h. psychological, physiological and neurological sequelae.
- 144. The said injuries suffered by ALYSSA GARGIULO, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein;
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances:
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;

- f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
- g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to different healthcare workers;
- h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
- i. allowed inappropriate flexible ordering of fentanyl;
- j. failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance;
- k. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
- failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;
- m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the mandatory obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- s. either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects;
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;

- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;
- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted;
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates, including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;
- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;
- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations.
- On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit B.

COUNT SEVENTEEN:

KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-145. Paragraphs 1 through 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FIVE (145), respectively, of this COUNT SEVENTEEN.
- 146. At all times mentioned herein, the plaintiff, KEITH ZACKOWITZ, was the husband of ALYSSA GARGIULO.
- 147. As a result of the aforesaid injuries of plaintiff ALYSSA GARGIULO, KEITH ZACKOWITZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT EIGHTEEN:

ALYSSA BARGIULO v. YALE UNIVERSITY

- 1-144. Paragraphs 1 through 143, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT EIGHTEEN.
- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11;
 - c. 21 C.F.R. § 1301.52(e);
 - d. 21 C.F.R. § 1301.91;
 - e. 21 C.F.R. §1304.04;
 - f. 21 C.F.R. § 1305.03;
 - g. 42 C.F.R. § 482.13;
 - h. 42 C.F.R. § 482.24;
 - i. 42 C.F.R. § 482.25;
 - j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");
 - k. Conn. Gen. Stat. § 21a-254;
 - 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT NINETEEN: KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-146. Paragraphs 1 through 146 of COUNT EIGHTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-SIX (146), respectively, of this COUNT NINETEEN.
- 147. At all times mentioned herein, the plaintiff, KEITH ZACKOWITZ, was the husband of ALYSSA GARGIULO.
- 148. As a result of the aforesaid injuries of plaintiff ALYSSA GARGIULO, KEITH ZACKOWITZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT TWENTY: ALYSSA GARGIULO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT TWENTY.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.
- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.
- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.
- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149-56. Paragraphs 144-151 of COUNT TWENTY-NINE are hereby incorporated and realleged as paragraphs ONE HUNDRED FORTY-NINE through ONE HUNDRED FIFTY-SIX (156) respectively, of this COUNT TWENTY.
- 157. YALE UNIVERSITY's breach of contract, as addressed in COUNT TWENTY-NINE and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.

- 158. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a et seq. ("CUTPA").
- 159. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 160. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT TWENTY-ONE:

KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-160. Paragraphs 1-160 of COUNT TWENTY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED SIXTY (160) respectively, of this COUNT TWENTY-ONE
- 161. At all times mentioned herein, the plaintiff, KEITH ZACKOWITZ, was the husband of ALYSSA GARGIULO.
- 162. As a result of the aforesaid injuries of plaintiff ALYSSA GARGIULO, KEITH ZACKOWITZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT TWENTY-TWO:

KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-151. Paragraphs 1-151 of COUNT THIRTY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-ONE (151), respectively, of this COUNT TWENTY-TWO.
- 152. YALE UNIVERSITY's breach of contract, as alleged in COUNT THIRTY and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 153. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").

- 154. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 155. As a result of YALE UNIVERSITY's violation of CUTPA, KEITH ZACKOWITZ suffered harm, including mental anguish and/or money damages.

COUNT TWENTY-THREE: ALYSSA GARGIULO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT TWENTY-THREE.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.
- 146. With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY;
 - c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.
- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.
- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:

- a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
- b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
- c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.

<u>COUNT TWENTY-FOUR:</u> <u>KEITH ZACKOWITZ v. YALE UNIVERSITY</u>

- 1-148. Paragraphs 1-148 of COUNT TWENTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-EIGHT (148) respectively, of this COUNT TWENTY-FOUR.
- 149. At all times mentioned herein, the plaintiff, KEITH ZACKOWITZ, was the husband of ALYSSA GARGIULO.
- 150. As a result of the aforesaid injuries of plaintiff ALYSSA GARGIULO, KEITH ZACKOWITZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT TWENTY-FIVE: ALYSSA GARGIULO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT TWENTY-FIVE.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.

- 146. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.
- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 150. On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. ability to carry on and enjoy life's activities;
 - g. expenses for medical care and treatment;
 - h. psychological, physiological and neurological sequelae.

COUNT TWENTY-SIX: KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-152. Paragraphs 1-152 of COUNT TWENTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-TWO (152), respectively, of this COUNT TWENTY-SIX.
- 153. At all times mentioned herein, the plaintiff, KEITH ZACKOWITZ, was the husband of ALYSSA GARGIULO.
- 154. As a result of the aforesaid injuries of plaintiff ALYSSA GARGIULO, KEITH ZACKOWITZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT TWENTY-SEVEN: ALYSSA GARGIULO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143), respectively, of this COUNT TWENTY-SEVEN.
- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.

- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.
- 154. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 155. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT TWENTY-EIGHT: KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-155. Paragraphs 1 through 155 of COUNT TWENTY-SEVEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FIVE (155), respectively, of this COUNT TWENTY-EIGHT.
- 156. At all times mentioned herein, the plaintiff, KEITH ZACKOWITZ, was the husband of ALYSSA GARGIULO.
- 157. As a result of the aforesaid injuries of plaintiff ALYSSA GARGIULO, KEITH ZACKOWITZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

<u>COUNT TWENTY-NINE:</u> ALYSSA GARGIULO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT TWENTY-NINE.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT THIRTY:

KEITH ZACKOWITZ v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTEEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT THIRTY.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff, KEITH ZACKOWITZ, under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff, KEITH ZACKOWITZ, agreed to pay and did pay

- substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. KEITH ZACKOWITZ performed the terms and conditions required of him under his contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, KEITH ZACKOWITZ, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened his objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff, KEITH ZACKOWITZ, suffered harm, including mental anguish and/or money damages.

COUNT THIRTY-ONE: BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-141. Paragraphs 1-141 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-ONE (141) respectively, of this COUNT THIRTY-ONE.
- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of BRIANNE MCLOUGHLIN for the same or similar condition, which included one or more oocyte retrievals performed in 2020.
- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, BRIANNE MCLOUGHLIN suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress:
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

- 144. The said injuries suffered by BRIANNE MCLOUGHLIN, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein;
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances;
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;
 - f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to different healthcare workers;
 - h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
 - i. allowed inappropriate flexible ordering of fentanyl;
 - j. failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance;
 - failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
 - failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;
 - m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
 - n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;

- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the mandatory obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects;
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;
- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;
- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted:
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates, including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;

- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;
- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations.
- On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit C.

COUNT THIRTY-TWO: MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-145. Paragraphs 1 through 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FIVE (145), respectively, of this COUNT THIRTY-TWO.
- 146. At all times mentioned herein, the plaintiff, MATTHEW MCLOUGHLIN, was the husband of BRIANNE MCLOUGHLIN.
- 147. As a result of the aforesaid injuries of plaintiff BRIANNE MCLOUGHLIN, MATTHEW MCLOUGHLIN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT THIRTY-THREE: BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-144. Paragraphs 1 through 143, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT THIRTY-THREE.
- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11;
 - c. 21 C.F.R. § 1301.52(e);

- d. 21 C.F.R. § 1301.91;
- e. 21 C.F.R. §1304.04;
- f. 21 C.F.R. § 1305.03;
- g. 42 C.F.R. § 482.13;
- h. 42 C.F.R. § 482.24;
- i. 42 C.F.R. § 482.25;
- j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");
- k. Conn. Gen. Stat. § 21a-254;
- 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT THIRTY-FOUR:

MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-146. Paragraphs 1 through 146 of THIRTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-SIX (146), respectively, of this COUNT THIRTY-FOUR.
- 147. At all times mentioned herein, the plaintiff, MATTHEW MCLOUGHLIN, was the husband of BRIANNE MCLOUGHLIN.
- 148. As a result of the aforesaid injuries of plaintiff BRIANNE MCLOUGHLIN, MATTHEW MCLOUGHLIN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT THIRTY-FIVE:

BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT THIRTY-FIVE.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.
- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.

- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.
- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149-56.Paragraphs 144-151 of COUNT FORTY-FOUR are hereby incorporated and realleged as paragraphs ONE HUNDRED FORTY-NINE through ONE HUNDRED FIFTY-SIX (156) respectively, of this COUNT THIRTY-FIVE.
- 157. YALE UNIVERSITY's breach of contract, as addressed in COUNT FORTY-FOUR and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 158. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a et seq. ("CUTPA").
- 159. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 160. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT THIRTY-SIX:

MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-160. Paragraphs 1-160 of COUNT THIRTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED SIXTY (160) respectively, of this COUNT THIRTY-SIX.
- 161. At all times mentioned herein, the plaintiff, MATTHEW MCLOUGHLIN, was the husband of BRIANNE MCLOUGHLIN.

162. As a result of the aforesaid injuries of plaintiff BRIANNE MCLOUGHLIN, MATTHEW MCLOUGHLIN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT THIRTY-SEVEN:

MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-151. Paragraphs 1-151 of COUNT FORTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-ONE (151), respectively, of this COUNT THIRTY-SEVEN.
- 152. YALE UNIVERSITY's breach of contract, as alleged in COUNT FORTY-FIVE and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 153. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 154. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 155. As a result of YALE UNIVERSITY's violation of CUTPA, MATTHEW MCLOUGHLIN suffered harm, including mental anguish and/or money damages.

COUNT THIRTY-EIGHT: BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT THIRTY-EIGHT.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.
- With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY;
 - c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.

- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.
- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:
 - a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
 - b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
 - c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.

COUNT THIRTY-NINE: MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-148. Paragraphs 1-148 of COUNT THIRTY-EIGHT are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-EIGHT (148) respectively, of this COUNT THIRTY-NINE.
- 149. At all times mentioned herein, the plaintiff, MATTHEW MCLOUGHLIN, was the husband of BRIANNE MCLOUGHLIN.

150. As a result of the aforesaid injuries of plaintiff BRIANNE MCLOUGHLIN, MATTHEW MCLOUGHLIN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FORTY: BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FORTY.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.
- The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.
- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;

- c. mental and emotional distress;
- d. loss of quality of life;
- e. impaired future earning capacity;
- f. ability to carry on and enjoy life's activities;
- g. expenses for medical care and treatment;
- h. psychological, physiological and neurological sequelae.

COUNT FORTY-ONE:

MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-152. Paragraphs 1-152 of COUNT FORTY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-TWO (152), respectively, of this COUNT FORTY-ONE.
- 153. At all times mentioned herein, the plaintiff, MATTHEW MCLOUGHLIN, was the husband of BRIANNE MCLOUGHLIN.
- 154. As a result of the aforesaid injuries of plaintiff BRIANNE MCLOUGHLIN, MATTHEW MCLOUGHLIN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FORTY-TWO:

BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143), respectively, of this COUNT FORTY-TWO.
- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.

- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.
- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.
- As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 155. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT FORTY-THREE: MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-155. Paragraphs 1 through 155 of COUNT FORTY-TWO are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FIVE (155), respectively, of this COUNT FORTY-THREE.
- 156. At all times mentioned herein, the plaintiff, MATTHEW MCLOUGHLIN, was the

- husband of BRIANNE MCLOUGHLIN.
- 157. As a result of the aforesaid injuries of plaintiff BRIANNE MCLOUGHLIN, MATTHEW MCLOUGHLIN has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FORTY-FOUR: BRIANNE MCLOUGHLIN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FORTY-FOUR.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT FORTY-FIVE:

MATTHEW MCLOUGHLIN v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT THIRTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FORTY-FIVE.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff, MATTHEW MCLOUGHLIN, under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.

- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff, MATTHEW MCLOUGHLIN, agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. MATTHEW MCLOUGHLIN performed the terms and conditions required of him under his contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, MATTHEW MCLOUGHLIN, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened his objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff, MATTHEW MCLOUGHLIN, suffered harm, including mental anguish and/or money damages.

COUNT FORTY-SIX: LEAH MIRAKHOR v. YALE UNIVERSITY

- 1-141. Paragraphs 1-141 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-ONE (141) respectively, of this COUNT FORTY-SIX.
- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of LEAH MIRAKHOR for the same or similar condition, which included one or more oocyte retrievals performed in 2020.
- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, LEAH MIRAKHOR suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;

- f. medical expenses;
- g. impaired future earning capacity
- h. psychological, physiological and neurological sequelae.
- 144. The said injuries suffered by LEAH MIRAKHOR, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein:
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances;
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;
 - f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to different healthcare workers;
 - h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
 - i. allowed inappropriate flexible ordering of fentanyl;
 - j. failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance;
 - k. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
 - failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;

- m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the mandatory obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- s. either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects;
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;
- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;
- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted;
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates,

- including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;
- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;
- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations.
- On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit D.

COUNT FORTY-SEVEN: NAVID HAFEZ v. YALE UNIVERSITY

- 1-145. Paragraphs 1 through 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FIVE (145), respectively, of this COUNT FORTY-SEVEN.
- 146. At all times mentioned herein, the plaintiff, NAVID HAFEZ, was the husband of LEAH MIRAKHOR.
- 147. As a result of the aforesaid injuries of plaintiff LEAH MIRAKHOR, NAVID HAFEZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FORTY-EIGHT: LEAH MIRAKHOR v. YALE UNIVERSITY

1-144. Paragraphs 1 through 143, 145 of FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT FORTY-EIGHT.

- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11;
 - c. 21 C.F.R. § 1301.52(e);
 - d. 21 C.F.R. § 1301.91;
 - e. 21 C.F.R. §1304.04;
 - f. 21 C.F.R. § 1305.03;
 - g. 42 C.F.R. § 482.13;
 - h. 42 C.F.R. § 482.24;
 - i. 42 C.F.R. § 482.25;
 - j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");
 - k. Conn. Gen. Stat. § 21a-254;
 - 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT FORTY-NINE:

NAVID HAFEZ v. YALE UNIVERSITY

- 1-146. Paragraphs 1 through 146 of COUNT FORTY-EIGHT are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-SIX (146), respectively, of this COUNT FORTY-NINE.
- 147. At all times mentioned herein, the plaintiff, NAVID HAFEZ, was the husband of LEAH MIRAKHOR.
- 148. As a result of the aforesaid injuries of plaintiff LEAH MIRAKHOR, NAVID HAFEZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FIFTY:

LEAH MIRAKHOR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FIFTY.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.

- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.
- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.
- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149-56. Paragraphs 144-151 of COUNT FIFTY-NINE are hereby incorporated and realleged as paragraphs ONE HUNDRED FORTY-NINE through ONE HUNDRED FIFTY-SIX (156) respectively, of this COUNT FIFTY.
- 157. YALE UNIVERSITY's breach of contract, as addressed in COUNT FIFTY-NINE and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 158. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 159. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 160. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT FIFTY-ONE:

NAVID HAFEZ v. YALE UNIVERSITY

1-160. Paragraphs 1-160 of COUNT FIFTY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED SIXTY (160) respectively, of this COUNT FIFTY-ONE.

- 161. At all times mentioned herein, the plaintiff, NAVID HAFEZ, was the husband of LEAH MIRAKHOR.
- 162. As a result of the aforesaid injuries of plaintiff LEAH MIRAKHOR, NAVID HAFEZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FIFTY-TWO: NAVID HAFEZ v. YALE UNIVERSITY

- 1-151. Paragraphs 1-151 of COUNT SIXTY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-ONE (151), respectively, of this COUNT FIFTY-TWO.
- 152. YALE UNIVERSITY's breach of contract, as alleged in COUNT SIXTY and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 153. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 154. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 155. As a result of YALE UNIVERSITY's violation of CUTPA, NAVID HAFEZ suffered harm, including mental anguish and/or money damages.

COUNT FIFTY-THREE: LEAH MIRAKHOR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FIFTY-THREE.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.
- 146. With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY;

- c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.
- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.
- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:
 - a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
 - b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
 - c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.

COUNT FIFTY-FOUR: NAVID HAFEZ v. YALE UNIVERSITY

1-148. Paragraphs 1-148 of COUNT FIFTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-EIGHT (148) respectively, of this COUNT FIFTY-FOUR.

- 149. At all times mentioned herein, the plaintiff, NAVID HAFEZ, was the husband of LEAH MIRAKHOR.
- 150. As a result of the aforesaid injuries of plaintiff LEAH MIRAKHOR, NAVID HAFEZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FIFTY-FIVE: LEAH MIRAKHOR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FIFTY-FIVE.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.
- 146. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.
- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 150. On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:

- a. terror;
- b. pain and suffering;
- c. mental and emotional distress;
- d. loss of quality of life;
- e. impaired future earning capacity;
- f. ability to carry on and enjoy life's activities;
- g. expenses for medical care and treatment;
- h. psychological, physiological and neurological sequelae.

COUNT FIFTY-SIX:

NAVID HAFEZ v. YALE UNIVERSITY

- 1-152. Paragraphs 1-152 of COUNT FIFTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-TWO (152), respectively, of this COUNT FIFTY-SIX.
- 153. At all times mentioned herein, the plaintiff, NAVID HAFEZ, was the husband of LEAH MIRAKHOR.
- 154. As a result of the aforesaid injuries of plaintiff LEAH MIRAKHOR, NAVID HAFEZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

<u>COUNT FIFTY-SEVEN:</u> <u>LEAH MIRAKHOR v. YALE UNIVERSITY</u>

- 1-143. Paragraphs 1-142, 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143), respectively, of this COUNT FIFTY-SEVEN.
- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.

- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.
- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.
- As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 155. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT FIFTY-EIGHT: NAVID HAFEZ v. YALE UNIVERSITY

- 1-155. Paragraphs 1 through 155 of COUNT FIFTY-SEVEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FIVE (155), respectively, of this COUNT FIFTY-EIGHT.
- 156. At all times mentioned herein, the plaintiff, NAVID HAFEZ, was the husband of LEAH MIRAKHOR.
- 157. As a result of the aforesaid injuries of plaintiff LEAH MIRAKHOR, NAVID HAFEZ has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT FIFTY-NINE: LEAH MIRAKHOR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT FIFTY-NINE.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT SIXTY:

NAVID HAFEZ v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT FORTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SIXTY.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff, NAVID HAFEZ, under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff, NAVID HAFEZ, agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. NAVID HAFEZ performed the terms and conditions required of him under his contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, NAVID HAFEZ, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened his objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff, NAVID HAFEZ, suffered harm, including mental anguish and/or money damages.

COUNT SIXTY-ONE:

DILAY NACAR v. YALE UNIVERSITY

- 1-141. Paragraphs 1-141 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-ONE (141) respectively, of this COUNT SIXTY-ONE.
- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of DILAY NACAR for the same or similar condition, which included one or more oocyte retrievals performed in 2020.

- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, DILAY NACAR suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity
 - h. psychological, physiological and neurological sequelae.
- 144. The said injuries suffered by DILAY NACAR, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein;
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances;
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;
 - f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to different healthcare workers;
 - h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
 - i. allowed inappropriate flexible ordering of fentanyl;

- j. failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance:
- k. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
- failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;
- m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the mandatory obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- s. either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects:
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;
- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;
- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted;
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of

- possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates, including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;
- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;
- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations;
- jj. failed to offer and provide appropriate anesthesiology services and pain management to plaintiff, who underwent an oocyte retrieval on a Saturday or Sunday.
- On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit E.

COUNT SIXTY-TWO: ALPEN NACAR v. YALE UNIVERSITY

1-145. Paragraphs 1 through 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FIVE (145), respectively, of this COUNT SIXTY-TWO.

- 146. At all times mentioned herein, the plaintiff, ALPEN NACAR, was the husband of DILAY NACAR.
- 147. As a result of the aforesaid injuries of plaintiff DILAY NACAR, ALPEN NACAR has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SIXTY-THREE: DILAY NACAR v. YALE UNIVERSITY

- 1-144. Paragraphs 1 through 143, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT SIXTY-THREE.
- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11;
 - c. 21 C.F.R. § 1301.52(e);
 - d. 21 C.F.R. § 1301.91;
 - e. 21 C.F.R. §1304.04;
 - f. 21 C.F.R. § 1305.03;
 - g. 42 C.F.R. § 482.13;
 - h. 42 C.F.R. § 482.24;
 - i. 42 C.F.R. § 482.25;
 - j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");
 - k. Conn. Gen. Stat. § 21a-254;
 - 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT SIXTY-FOUR:

ALPEN NACAR v. YALE UNIVERSITY

- 1-146. Paragraphs 1 through 146 of COUNT SIXTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-SIX (146), respectively, of this COUNT SIXTY-FOUR.
- 147. At all times mentioned herein, the plaintiff, ALPEN NACAR, was the husband of DILAY NACAR.

148. As a result of the aforesaid injuries of plaintiff DILAY NACAR, ALPEN NACAR has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SIXTY-FIVE: DILAY NACAR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SIXTY-FIVE.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.
- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.
- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.
- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its performance of oocyte retrieval procedures on weekends or holidays without anesthesiology services increased the likelihood that diversion would take place at those times, result in inadequate pain management, and pose an unreasonable and egregious risk of physical injury to its patients.
- 150. Upon information and belief, YALE UNIVERSITY made the business decision to not offer anesthesiology services for oocyte retrievals performed on weekends or holidays to reduce costs and/or maximize profits.
- 151. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of offering anesthesiology services for oocyte retrievals only on weekdays and non-holidays was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 152-159. Paragraphs 144-151 of COUNT SEVENTY-FOUR are hereby incorporated and realleged as paragraphs ONE HUNDRED FIFTY-TWO through ONE HUNDRED FIFTY-NINE (159) respectively, of this COUNT SIXTY-FIVE.

- 160. YALE UNIVERSITY's breach of contract, as addressed in COUNT SEVENTY-FOUR and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 161. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a et seq. ("CUTPA").
- 162. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 163. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT SIXTY-SIX:

ALPEN NACAR v. YALE UNIVERSITY (without anesth)

- 1-163. Paragraphs 1-163 of COUNT SIXTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED SIXTY-THREE (163), respectively, of this COUNT SIXTY-SIX.
- 164. At all times mentioned herein, the plaintiff, ALPEN NACAR, was the husband of DILAY NACAR.
- 165. As a result of the aforesaid injuries of plaintiff DILAY NACAR, ALPEN NACAR has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SIXTY-SEVEN:

ALPEN NACAR v. YALE UNIVERSITY

- 1-151. Paragraphs 1-151 of COUNT SEVENTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-ONE (151), respectively, of this COUNT SIXTY-SEVEN.
- 152. YALE UNIVERSITY's breach of contract, as alleged in SEVENTY-FIVE and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.

- 153. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 154. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 155. As a result of YALE UNIVERSITY's violation of CUTPA, ALPEN NACAR suffered harm, including mental anguish and/or money damages.

COUNT SIXTY-EIGHT: DILAY NACAR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SIXTY-EIGHT.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.
- 146. With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY;
 - c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.
- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:
 - a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
 - b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
 - c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.
 - d. YALE UNIVERSITY prioritized and effectuated its own interests—including its interests in cost-reduction and profit maximization—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it failed to provide anesthesiology services to patients undergoing oocyte retrievals on Saturdays, Sundays, and holidays.

COUNT SIXTY-NINE: ALPEN NACAR v. YALE UNIVERSITY

- 1-148. Paragraphs 1-148 of COUNT SIXTY-EIGHT are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-EIGHT (148) respectively, of this COUNT SIXTY-NINE.
- 149. At all times mentioned herein, the plaintiff, ALPEN NACAR, was the husband of DILAY NACAR.
- 150. As a result of the aforesaid injuries of plaintiff DILAY NACAR, ALPEN NACAR has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SEVENTY: DILAY NACAR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SEVENTY.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.
- 146. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.
- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 150. On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;

- e. impaired future earning capacity;
- f. ability to carry on and enjoy life's activities;
- g. expenses for medical care and treatment;
- h. psychological, physiological and neurological sequelae.

COUNT SEVENTY-ONE: ALPEN NACAR v. YALE UNIVERSITY

- 1-152. Paragraphs 1-152 of COUNT SEVENTY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-TWO (152), respectively, of this COUNT SEVENTY-ONE.
- 153. At all times mentioned herein, the plaintiff, ALPEN NACAR, was the husband of DILAY NACAR.
- 154. As a result of the aforesaid injuries of plaintiff DILAY NACAR, ALPEN NACAR has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SEVENTY-TWO: DILAY NACAR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143), respectively, of this COUNT SEVENTY-TWO.
- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.

- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.
- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.
- 154. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 155. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT SEVENTY-THREE: ALPEN NACAR v. YALE UNIVERSITY

- 1-155. Paragraphs 1 through 155 of COUNT SEVENTY-TWO are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FIVE (155), respectively, of this COUNT SEVENTY-THREE.
- 156. At all times mentioned herein, the plaintiff, ALPEN NACAR, was the husband of DILAY NACAR.

157. As a result of the aforesaid injuries of plaintiff DILAY NACAR, ALPEN NACAR has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT SEVENTY-FOUR: DILAY NACAR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SEVENTY-FOUR.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT SEVENTY-FIVE: ALPEN NACAR v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SIXTY-ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SEVENTY-FIVE.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff, ALPEN NACAR, under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.

- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff, ALPEN NACAR, agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. ALPEN NACAR performed the terms and conditions required of him under his contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, ALPEN NACAR, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened his objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff, ALPEN NACAR, suffered harm, including mental anguish and/or money damages.

COUNT SEVENTY-SIX: AWO OSAFO-ADDO v. YALE UNIVERSITY

- 1-141. Paragraphs 1-141 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-ONE (141) respectively, of this COUNT SEVENTY-SIX.
- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of AWO OSAFO-ADDO for the same or similar condition, which included one or more oocyte retrievals performed in 2020.
- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, AWO OSAFO-ADDO suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;

- f. medical expenses;
- g. impaired future earning capacity
- h. psychological, physiological and neurological sequelae.
- 144. The said injuries suffered by AWO OSAFO-ADDO, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein;
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances;
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;
 - f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to different healthcare workers;
 - h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
 - i. allowed inappropriate flexible ordering of fentanyl;
 - j. failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance;
 - k. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
 - failed, upon information and belief, to audit bulk transactions to document a chain of custody for every milligram of controlled substance received, transferred, or disposed;

- m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the mandatory obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- s. either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects;
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;
- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;
- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted:
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates,

- including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;
- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;
- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations.
- On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit F.

COUNT SEVENTY-SEVEN: AWO OSAFO-ADDO v. YALE UNIVERSITY

- 1-144. Paragraphs 1 through 143, 145 of COUNT SEVENTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT SEVENTY-SEVEN.
- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11;
 - c. 21 C.F.R. § 1301.52(e);
 - d. 21 C.F.R. § 1301.91;
 - e. 21 C.F.R. §1304.04;
 - f. 21 C.F.R. § 1305.03;
 - g. 42 C.F.R. § 482.13;
 - h. 42 C.F.R. § 482.24;
 - i. 42 C.F.R. § 482.25;
 - j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");

- k. Conn. Gen. Stat. § 21a-254;
- 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT SEVENTY-EIGHT: AWO OSAFO-ADDO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SEVENTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SEVENTY-EIGHT.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.
- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.
- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.
- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149-56. Paragraphs 144-151 of COUNT EIGHTY-TWO are hereby incorporated and realleged as paragraphs ONE HUNDRED FORTY-NINE through ONE HUNDRED FIFTY-SIX (156) respectively, of this COUNT SEVENTY-EIGHT.
- 157. YALE UNIVERSITY's breach of contract, as addressed in COUNT EIGHTY-TWO and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 158. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a et seq. ("CUTPA").

- 159. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 160. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT SEVENTY-NINE: AWO OSAFO-ADDO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SEVENTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT SEVENTY-NINE.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.
- 146. With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY:
 - c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.
- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;

- e. loss of enjoyment of life's activities;
- f. medical expenses;
- g. impaired future earning capacity;
- h. psychological, physiological and neurological sequelae.
- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:
 - a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
 - b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
 - c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.

COUNT EIGHTY: AWO OSAFO-ADDO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SEVENTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT EIGHTY.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.
- 146. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.

- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 150. On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. ability to carry on and enjoy life's activities;
 - g. expenses for medical care and treatment;
 - h. psychological, physiological and neurological sequelae.

COUNT EIGHTY-ONE:

AWO OSAFO-ADDO v. YALE UNIVERSITY

1-143. Paragraphs 1-142, 145 of COUNT SEVENTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143), respectively, of this COUNT EIGHTY-ONE.

- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.
- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror:
 - b. pain and suffering;
 - c. mental and emotional distress:
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.

- As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 155. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT EIGHTY-TWO: AWO OSAFO-ADDO v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT SEVENTY-SIX are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT EIGHTY-TWO.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT EIGHTY-THREE: NICOLE WALSH v. YALE UNIVERSITY

1-141. Paragraphs 1-141 of COUNT ONE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-ONE (141) respectively, of this COUNT EIGHTY-THREE.

- 142. At all times that plaintiff was a patient of YALE UNIVERITY's REI Clinic, YALE UNIVERSITY undertook the care, treatment, monitoring, diagnosing, and supervision of NICOLE WALSH for the same or similar condition, which included one or more oocyte retrievals performed in 2020.
- 143. While under the care, treatment, monitoring, diagnosing, and supervision of YALE UNIVERSITY, NICOLE WALSH suffered the following severe, serious, painful, and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity
 - h. psychological, physiological and neurological sequelae.
- 144. The said injuries suffered by NICOLE WALSH, as alleged in the preceding paragraph, were caused by the failure of YALE UNIVERSITY to exercise reasonable care under all the facts and circumstances then and there present in one or more of the following ways in that it:
 - a. failed to properly diagnose, care for, and treat plaintiff, as set forth herein;
 - b. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to prevent, identify, detect, evaluate, investigate, and/or respond to opioid diversion/substitution;
 - c. failed to regularly review or update policies and procedures to prevent and timely detect the diversion of controlled substances;
 - d. failed to devise, institute, and/or enforce proper policies, procedures, and/or systems to identify, evaluate, investigate, and/or intervene with opioid diversion/substitution;
 - e. failed to devise, institute, and/or enforce policies, procedures, and/or systems to prevent clinicians from additionally serving in the roles of opioid ordering, inventorying, and/or storage;
 - f. failed to utilize two healthcare workers—one of whom was a licensed pharmacy professional—to witness the delivery and inventory of controlled substances;
 - g. failed to separate the duties of controlled substance ordering and receipt of controlled-substance purchase orders to different healthcare workers;
 - h. failed, upon information and belief, to obtain a complete inventory that identifies the drug name, dosage form, drug strength, quantity, and date transferred, in

- violation of Medicare Condition of Participation and DEA Regulations, see, e.g., 21 C.F.R. 1304.11; 21 C.F.R. 1301.52(e)(1);
- i. allowed inappropriate flexible ordering of fentanyl;
- j. failed to devise, institute and/or enforce policies, procedures, and/or systems for the proper storage of controlled substances, including fentanyl, a Schedule II controlled substance;
- k. failed, upon information and belief, to create, submit, and/or maintain appropriate records attending the procurement of opioids at the clinic, including but not limited to DEA Form 222 or an electronic equivalent;
- failed, upon information and belief, to audit bulk transactions to document a chain
 of custody for every milligram of controlled substance received, transferred, or
 disposed;
- m. failed to minimize excess stock of opioids stored at the REI Clinic to reduce the total quantity of drugs susceptible to diversion;
- n. failed to screen and rescreen employees for risk factors and behavioral indicators of diversion;
- o. failed to implement appropriate drug testing/screening, particularly for healthcare works who work in areas that are at elevated risk for diversion;
- p. failed to educate employees/agents on diversion, including the mandatory obligation of healthcare workers to report suspected diversion;
- q. failed to complete mandated supervised inventory checks of stored fentanyl;
- r. failed to appropriately inspect controlled substance inventory for tampering;
- s. either ignored or disregarded plaintiffs' complaints of excruciating pain that were not alleviated by additional doses of medication—a cardinal feature of opioid diversion;
- t. failed to report a suspicion that Nurse Donna Monticone was practicing while impaired or diverting fentanyl;
- u. failed to regularly assess patients to ensure that medications, including fentanyl, had its intended effects;
- v. failed to conduct audits of opioid administered in surgical and procedure areas at the end of every shift;
- w. failed, upon information and belief, to have two healthcare workers observe the wastage of controlled substances in real time with a visual line of sight;
- x. failed, upon information and belief, to have every discrepancy between administration and waste documentation be readily or immediately resolved, as required by federal regulations;

- y. failed, upon information and belief, to audit wasted or unused controlled substances using assay technologies, to confirm the identity and concentration of controlled substances that were documented as wasted;
- z. failed to establish a diversion investigation team to audit the distribution of controlled substances and opioids, including fentanyl, and to investigate reports of possible diversion within the Yale-New Haven Health System, including the REI Clinic;
- aa. failed to adequately train, educate, or instruct its servant(s), agent(s), apparent agent(s), and/or employee(s) to appropriately prevent, evaluate, investigate, intervene, and/or report concerns of opioid diversion/substitution;
- bb. improperly permitted "flexible ordering," for fentanyl;
- cc. failed to take appropriate remedial actions in response to controlled substance diversion/substitution events at YALE UNIVERSITY and/or partners/affiliates, including those resulting in the arrest of YALE UNIVERSITY employees and/or partners/affiliates in 2016 and 2019;
- dd. failed to properly examine opioids for signs of tampering, diversion, and substitution between each and every stage of medication use, including opioid dispensing and administration;
- ee. failed to properly investigate patient reports of excruciating pain, despite the documentation of fentanyl administration;
- ff. failed to investigate and/or properly respond to reports of uncontrolled pain or inadequate pain relief at the REI Clinic when fentanyl was administered by or in the presence of Nurse Donna Monticone;
- gg. failed to properly supervise and/or monitor Nurse Donna Monticone;
- hh. failed, upon information and belief, to investigate, address and/or properly respond to reports that Nurse Donna Monticone appeared incapacitated or impaired during her treatment of patients;
- ii. failed to create and/or maintain adequate medical records in accordance with Section 19a-14-40 *et seq.* of the Connecticut Department of Public Health and Addiction Services Regulations;
- jj. failed to offer and provide appropriate anesthesiology services and pain management to plaintiff, who underwent an oocyte retrieval on a Saturday or Sunday.
- On or about April 8, 2021, pursuant to Connecticut General Statutes § 52-190a(b), an automatic ninety (90) day extension of the applicable statutes of limitations was filed with and granted by the Superior Court. A copy of said petition is attached hereto as Exhibit G.

<u>COUNT EIGHTY-FOUR:</u> <u>GARY WALSH v. YALE UNIVERSITY</u>

- 1-145. Paragraphs 1 through 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FIVE (145), respectively, of this COUNT EIGHTY-FOUR.
- 146. At all times mentioned herein, the plaintiff, GARY WALSH, was the husband of NICOLE WALSH.
- 147. As a result of the aforesaid injuries of plaintiff NICOLE WALSH, GARY WALSH has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

<u>COUNT EIGHTY-FIVE:</u> <u>NICOLE WALSH v. YALE UNIVERSITY</u>

- 1-144. Paragraphs 1 through 143, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-FOUR (144) respectively, of this COUNT EIGHTY-FIVE.
- 145. The said injuries suffered by plaintiff, as alleged herein, were caused by the failure of YALE UNIVERSITY to follow each and every statutory duty or duties, individually and in concert with one or more other identified statutory duty, listed below:
 - a. 21 U.S.C. § 827(b);
 - b. 21 C.F.R. § 1304.11:
 - c. 21 C.F.R. § 1301.52(e);
 - d. 21 C.F.R. § 1301.91;
 - e. 21 C.F.R. §1304.04;
 - f. 21 C.F.R. § 1305.03;
 - g. 42 C.F.R. § 482.13;
 - h. 42 C.F.R. § 482.24;
 - i. 42 C.F.R. § 482.25;
 - j. Conn. Gen. Stat. § 42-110a et seq. ("CUTPA");
 - k. Conn. Gen. Stat. § 21a-254;
 - 1. Regs. Conn. St. Agencies § 21a-262-6.
- 146. For each and every statutory duty identified in the previous paragraph:
 - a. The statutory duty was designed to protect patients from injury;
 - b. The plaintiff is within the class of persons for whose benefit and protection the statutory duty was enacted;
 - c. The plaintiff has suffered an injury for which the statutory duty was intended to guard against.

COUNT EIGHTY-SIX: GARY WALSH v. YALE UNIVERSITY

- 1-146. Paragraphs 1 through 146 of COUNT EIGHTY-FIVE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-SIX (146), respectively, of this COUNT EIGHTY-SIX.
- 147. At all times mentioned herein, the plaintiff, GARY WALSH, was the husband of NICOLE WALSH.
- 148. As a result of the aforesaid injuries of plaintiff NICOLE WALSH, GARY WALSH has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT EIGHTY-SEVEN: NICOLE WALSH v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT EIGHTY-SEVEN.
- 144. YALE UNIVERSITY knew, or should have known, of all of the foregoing information alleged at Paragraphs 1-142.
- 145. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its pursuit of bulk ordering of controlled substances, including opioids such as fentanyl, posed an unreasonable and egregious risk of physical injury to others.
- 146. YALE UNIVERSITY knew or should have known that hospitals, outpatient surgical centers, and outpatient medical facilities are particularly vulnerable to, and frequently the targets of opioid diversion and opioid substitution.
- 147. Upon information and belief, YALE UNIVERSITY made the business decision to pursue bulk ordering of controlled substances, including opioids such as fentanyl, to reduce costs and/or maximize profits.
- 148. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of ordering controlled substances, including opioids such as fentanyl, in bulk for storage at the REI Clinic was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 149. Based on this and similar information, YALE UNIVERSITY knew, or should have known, that its performance of oocyte retrieval procedures on weekends or holidays without anesthesiology services increased the likelihood that diversion would take place at those times, result in inadequate pain management, and pose an unreasonable and egregious risk of physical injury to its patients.
- 150. Upon information and belief, YALE UNIVERSITY made the business decision to not offer anesthesiology services for oocyte retrievals performed on weekends or holidays to reduce costs and/or maximize profits.

- 151. YALE UNIVERSITY's engagement in the cost-reduction or profit-maximizing strategy of offering anesthesiology services for oocyte retrievals only on weekdays and non-holidays was carried out in the course of YALE UNIVERSITY's trade or commerce.
- 152-59. Paragraphs 144-151 of COUNT NINETY-SIX are hereby incorporated and realleged as paragraphs ONE HUNDRED FIFTY-TWO through ONE HUNDRED FIFTY-NINE (159) respectively, of this COUNT EIGHTY-SEVEN.
- 160. YALE UNIVERSITY's breach of contract, as addressed in COUNT NINETY-SIX and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 161. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a et seq. ("CUTPA").
- 162. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 163. As a result of YALE UNIVERSITY's violation of CUTPA, plaintiff suffered the following injuries and losses:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress;
 - d. loss of quality of life;
 - e. loss of enjoyment of life's activities;
 - f. medical expenses;
 - g. impaired future earning capacity;
 - h. psychological, physiological and neurological sequelae.

COUNT EIGHTY-EIGHT:

GARY WALSH v. YALE UNIVERSITY (without anesth)

- 1-163. Paragraphs 1-163 of COUNT EIGHTY-SEVEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED SIXTY-THREE (163) respectively, of this COUNT EIGHTY-EIGHT
- 164. At all times mentioned herein, the plaintiff, GARY WALSH, was the husband of NICOLE WALSH.
- 165. As a result of the aforesaid injuries of plaintiff NICOLE WALSH, GARY WALSH has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT EIGHTY-NINE: GARY WALSH v. YALE UNIVERSITY

- 1-151. Paragraphs 1-151 of COUNT NINETY-SEVEN are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-ONE (151), respectively, of this COUNT EIGHTY-NINE.
- 152. YALE UNIVERSITY's breach of contract, as alleged in COUNT NINETY-SEVEN and reproduced herein, were so unfair or offensive that it constituted a violation of CUTPA.
- 153. Upon information and belief, YALE UNIVERSITY's conduct as previously alleged constituted a negligent, reckless, or knowing violation of the Connecticut Unfair Trade Practices Act, Connecticut General Statutes Section 42-110a *et seq.* ("CUTPA").
- 154. YALE UNIVERSITY's conduct, as previously alleged, was a substantial factor resulting in the injuries and suffering of the plaintiff, as further described in the following paragraph.
- 155. As a result of YALE UNIVERSITY's violation of CUTPA, GARY WALSH suffered harm, including mental anguish and/or money damages.

COUNT NINETY:

NICOLE WALSH v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT NINETY.
- 144. Fertility services, including oocyte retrievals, is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 145. At all relevant times herein, plaintiff placed a high degree of trust and confidence in YALE UNIVERSITY to provide such fertility services.
- 146. With regard to the allegations contained herein, there existed between YALE UNIVERSITY and plaintiff a continuing special and/or fiduciary relationship/duty characterized by:
 - a. plaintiff's unique degree of trust and confidence in YALE UNIVERSITY;
 - b. superior knowledge, skill, expertise, and/or position on the part of YALE UNIVERSITY;
 - c. a continuing duty imposed on YALE UNIVERSITY to represent the interests of plaintiff.
- 147. As a result of the breach of the special and/or fiduciary relationship/duty between YALE UNIVERSITY and plaintiff, the latter has suffered serious, painful and permanent injuries:
 - a. terror;

- b. pain and suffering;
- c. mental and emotional distress;
- d. loss of quality of life;
- e. loss of enjoyment of life's activities;
- f. medical expenses;
- g. impaired future earning capacity;
- h. psychological, physiological and neurological sequelae.
- 148. The said injuries suffered by plaintiff were caused by the intentional, knowing, reckless, or negligent breach of the special and/or fiduciary relationship/duty owed by YALE UNIVERSITY to plaintiff in one or more of the following ways:
 - a. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it engaged in a cost-reduction strategy whereby controlled substances, including fentanyl, were ordered in bulk and stored at the REI Clinic without proper oversight, or necessary diversion-prevention and diversion-detection measures.
 - b. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it appointed and entrusted Nurse Donna Monticone to manage its fentanyl stores while also engaging in direct patient care responsibilities.
 - c. YALE UNIVERSITY prioritized and effectuated its own interests—including its interest in maximizing profitability of REI Clinic services and interest in cost-reduction—over the interests of plaintiff to receive quality and safe care, particularly during oocyte retrievals, when it stored fentanyl at the REI Clinic in violation of federal and/or state law.

COUNT NINETY-ONE: GARY WALSH v. YALE UNIVERSITY

- 1-148. Paragraphs 1-148 of COUNT NINETY are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-EIGHT (148) respectively, of this COUNT NINETY-ONE.
- 149. At all times mentioned herein, the plaintiff, GARY WALSH, was the husband of NICOLE WALSH.
- 150. As a result of the aforesaid injuries of plaintiff NICOLE WALSH, GARY WALSH has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT NINETY-TWO: NICOLE WALSH v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT NINETY-TWO.
- 144. As part of its fertility treatment services, YALE UNIVERSITY recommended that plaintiff undergo an oocyte retrieval with administration of the analgesic, fentanyl.
- 145. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the nature of the oocyte retrieval.
- 146. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the risks and hazards of the procedure.
- 147. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the anticipated benefits of the oocyte retrieval.
- 148. The use of fentanyl for analgesia during the oocyte retrieval was material to YALE UNIVERSITY's informed disclosure to plaintiff of the alternatives to oocyte retrieval.
- 149. On or before the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY did not provide informed disclose to plaintiff of the nature, risks and hazards, alternatives, or anticipated benefits of oocyte retrieval in plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 150. On the dates that plaintiff underwent an oocyte retrieval at the REI Clinic, YALE UNIVERSITY inserted a large-bore needle through the vaginal wall and other anatomical structures of plaintiff with no fentanyl, or fentanyl that had been substituted or diluted with another agent.
- 151. While under the care of YALE UNIVERSITY, plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 152. As a result of the failure of YALE UNIVERSITY to provide informed disclosure and obtain proper consent for the oocyte retrieval, plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress:
 - d. loss of quality of life;

- e. impaired future earning capacity;
- f. ability to carry on and enjoy life's activities;
- g. expenses for medical care and treatment;
- h. psychological, physiological and neurological sequelae.

COUNT NINETY-THREE: GARY WALSH v. YALE UNIVERSITY

- 1-152. Paragraphs 1-152 of COUNT NINETY-TWO are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-TWO (152), respectively, of this COUNT NINETY-THREE.
- 153. At all times mentioned herein, the plaintiff, GARY WALSH, was the husband of NICOLE WALSH.
- 154. As a result of the aforesaid injuries of plaintiff NICOLE WALSH, GARY WALSH has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT NINETY-FOUR: NICOLE WALSH v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143), respectively, of this COUNT NINETY-FOUR.
- 144. An oocyte retrieval with administration of the analgesic, fentanyl, is a different and distinct medical procedure from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 145. The nature of an oocyte retrieval with the administration of fentanyl is different and distinct from an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 146. The risks and hazards of an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 147. The alternatives to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.
- 148. The anticipated benefits to an oocyte retrieval with the administration of fentanyl are different and distinct from those of an oocyte retrieval where no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline, is administered.

- 149. At no time, prior to plaintiff's respective oocyte retrievals, did YALE UNIVERSITY provide informed disclosure to plaintiff or obtain proper consent from plaintiff to complete an oocyte retrieval with no fentanyl, or fentanyl that had been substituted or diluted with another agent, such as saline.
- 150. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY completed the oocyte retrieval(s) on plaintiff with no fentanyl or fentanyl that had been substituted or diluted with another agent, such as saline.
- 151. On each and every date of plaintiff's respective oocyte retrieval, YALE UNIVERSITY performed a nonconsensual touching on plaintiff.
- 152. While under the care of YALE UNIVERSITY, the plaintiff suffered serious, severe, painful and permanent injuries set forth in the subsequent paragraph.
- 153. As a result of the medical assault and/or battery by YALE UNIVERSITY, on each and every date of the plaintiff's oocyte retrieval(s), the plaintiff suffered the following severe, serious, painful and permanent injuries:
 - a. terror;
 - b. pain and suffering;
 - c. mental and emotional distress:
 - d. loss of quality of life;
 - e. impaired future earning capacity;
 - f. psychological, physiological and neurological sequelae.
- As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has been permanently deprived of her ability to carry on and enjoy life's activities.
- 155. As a further result of the medical assault and/or battery by YALE UNIVERSITY on each and every date of the plaintiff's respective oocyte retrieval(s), the plaintiff has incurred expenses for medical care and treatment to her financial loss.

COUNT NINETY-FIVE: GARY WALSH v. YALE UNIVERSITY

- 1-155. Paragraphs 1 through 155 of COUNT NINETY-FOUR are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FIFTY-FIVE (155), respectively, of this COUNT NINETY-FIVE.
- 156. At all times mentioned herein, the plaintiff, GARY WALSH, was the husband of NICOLE WALSH.

157. As a result of the aforesaid injuries of plaintiff GARY WALSH, GARY WALSH has been deprived of the consortium, companionship, and society of his spouse, all to his damage.

COUNT NINETY-SIX: NICOLE WALSH v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT NINETY-SIX.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.
- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. Plaintiff performed the terms and conditions required of her under her contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened their objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff suffered harm, including mental anguish and/or money damages.

COUNT NINETY-SEVEN: GARY WALSH v. YALE UNIVERSITY

- 1-143. Paragraphs 1-142, 145 of COUNT EIGHTY-THREE are hereby incorporated and realleged as paragraphs ONE through ONE HUNDRED FORTY-THREE (143) respectively, of this COUNT NINETY-SEVEN.
- 144. YALE UNIVERSITY entered into contracts with the plaintiff, GARY WALSH, under which YALE UNIVERSITY agreed to provide anesthesia and/or sedation for oocyte retrievals.

- 145. A contract involving oocyte retrievals and the in vitro fertilization process is highly personal and implicates vital concerns regarding parenthood, procreation and assisting others to achieve their family plans.
- 146. In consideration of YALE UNIVERSITY's promises, including performance of oocyte retrievals under anesthesia, plaintiff, GARY WALSH, agreed to pay and did pay substantial sums for the services rendered or exhausted covered round(s) under their insurance plans.
- 147. GARY WALSH performed the terms and conditions required of him under his contract(s) with YALE UNIVERSITY.
- 148. Based on the conduct described herein, YALE UNIVERSITY breached its contract with plaintiff, GARY WALSH, including the incorporated contractual covenant of good faith and fair dealing.
- 149. YALE UNIVERSITY's failure to administer anesthesia and/or sedation deprived the plaintiff of the fruits of the contracts and contravened his objectively reasonable expectations under the contract.
- 150. A contract whereby a fertility clinic undertakes to perform an oocyte retrieval is one as to which it is reasonably foreseeable that breach thereof will cause mental anguish to the person or persons who entrusted the clinic with this procedure.
- 151. As a direct and proximate cause of YALE UNIVERSITY's breach of contract, the plaintiff, GARY WALSH, suffered harm, including mental anguish and/or money damages.

WHEREFORE, the plaintiffs claim:

- 1. Compensatory damages;
- 2. Punitive Damages;
- 3. Attorneys' Fees;
- 4. Costs; and
- 5. The Court enter such other relief as is deemed just and appropriate.

PLAINTIFFS MELISSA COWAN, ET AL.,

Joshuz D./Koskoff

Jeffrey W. Wisner Kelly A. Fitzpatrick

Koskoff, Koskoff & Bieder, P.C. 350 Fairfield Avenue, 5th Floor

Bridgeport, CT 06604 Tele:(203)336-4421

Fax: (203)368-3244

RETURN DATE: NOVEMBER 30, 2021 SUPERIOR COURT

MELISSA COWAN, JUDICIAL DISTRICT OF :

ALYSSA GARGIULO, : WATERBURY

BRIANNE MCLOUGHLIN,

LEAH MIRAKHOR, AT WATERBURY

DILAY NACAR, AWO OSAFO-ADDO, NICOLE WASH, MICHAEL COWAN, KEITH ZACKOWITZ, MATTHEW MCLOUGHLIN, NAVID HAFEZ,

ALPEN NACAR, and

GARY WALSH

V.

YALE UNIVERSITY : **NOVEMBER 5, 2021**

STATEMENT OF AMOUNT IN DEMAND

The amount of money damages claimed is greater than Fifteen Thousand Dollars (\$15,000.00), exclusive of interest and costs.

> **PLAINTIFFS** MELISSA COWAN, ET AL.,

Joshua D. Koskoff

Jeffrey W. Wisner

Kelly A. Fitzpatrick

Koskoff, Koskoff & Bieder, P.C. 350 Fairfield Avenue, 5th Floor

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Tele:(203)336-4421

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RETURN DATE: NOVEMBER 30, 2021 : SUPERIOR COURT

MELISSA COWAN, : JUDICIAL DISTRICT OF

ALYSSA GARGIULO, : WATERBURY

BRIANNE MCLOUGHLIN.

LEAH MIRAKHOR, : AT WATERBURY

DILAY NACAR,

AWO OSAFO-ADDO, NICOLE WASH, MICHAEL COWAN, KEITH ZACKOWITZ,

MATTHEW MCLOUGHLIN,

NAVID HAFEZ,

ALPEN NACAR, and GARY WALSH

v.

YALE UNIVERSITY

November 5, 2021

CERTIFICATION

I, JEFFREY WISNER, hereby certify that I have made reasonable inquiry, as permitted by the circumstances, to determine whether there are grounds for a good faith belief that there has been negligence in the care and treatment of MELISSA COWAN, ALYSSA GARGIULO, BRIANNE MCLOUGHLIN, LEAH MIRAKHOR, DILAY NACAR, AWO OSAFO-ADDO, and NICOLE WALSH. This inquiry has given rise to a good faith belief on my part that grounds exist for an action against the defendants, YALE UNIVERSITY and/or its servants, agents, apparent agents and/or employees.

THE PLAINTIFF,

BY:

JEFFREY WISNER

KOSKOFF, KOSKOFF & BIEDER, PC

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

TELEPHONE NO: 203.336.4421

JURIS NO. 032250

Dear Attorney Wisner,

Thank you for asking me to review this potential case against Yale University. As you are aware, this case involves the care rendered to women during egg retrieval surgeries at the Yale REI Clinic in Orange, CT from the end of May, 2020 through late October, 2020.

As you are aware, I am a drug diversion prevention specialist who has worked in this field since November 2015. In this capacity, I manage the drug diversion prevention program at a major academic health center in Michigan, which included instituting drug diversion prevention measures at off-campus outpatient reproduction and endocrinology clinics. I have achieved a Bachelor of Science in Nursing, a Master of Science in Nursing and have additional experience as a nursing supervisor. I am a certified nurse manager and leader and a member of the International Health Facility Diversion Association. I am a registered nurse and possess the necessary credentials and/or licensure to practice as a specialist in drug diversion prevention in Michigan, which you informed me are the same or greater than those required by the State of Connecticut.

In addition to my knowledge and experience, I relied on the following as part of my prelitigation review of this matter:

- The United States' May 18, 2021, Sentencing Memorandum of Donna Monticone, which detailed Nurse Monticone's admitted diversion of at least 75% of fentanyl stores at the Yale REI Clinic in Orange, CT during a five-month period in 2020. This Memorandum documented how Nurse Monticone replaced fentanyl with saline, knowing that saline (water) would be administered to patients instead of fentanyl, a potent analgesic.
- This memorandum additionally detailed how Ms. Monticone was responsible for fentanyl ordering and inventorying, without basic system-level safeguards inherent in segregation of duties. It also noted that the room where the fentanyl was stored at the Yale REI Clinic (Orange Location) was not always locked, thereby reducing measures to prevent diversion.
- The report of Attorney Wisner that dozens of women reported significant and uncontrolled pain during their respective egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation recording the administration of fentanyl for analgesia.
- The medical records of women plaintiffs in this matter who were treated at the Yale REI Clinic in Orange, CT during the period in question, which indicated that each woman was documented as receiving fentanyl during a respective egg retrieval surgery.

From this review, it is my opinion that there is a good faith basis to support negligence on the part of the defendant, Yale New-Haven Hospital and/or Yale University. The standard of care required the defendant to institute drug diversion prevention strategies to prevent the tampering and substitution of fentanyl – an opioid 50 to 100 times more potent than morphine – in its facilities.

As evidenced by the May 18, 2021, Sentencing Memorandum, the Yale REI Clinic failed to maintain effective controls and procedures to guard against theft and diversion of fentanyl.

The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

Sincerely,			

Dear Attorney Wisner,

Thank you for asking me to review the case of Nicole Walsh. This case involves the care that Nicole Walsh received at the Yale REI Clinic in Orange, CT for a May 30, 2020 egg retrieval surgery.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone admitted to adulterating at least 75% of all fentanyl administered at the clinic during a five month period, diluting or entirely replacing the fentanyl with saline (water). It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card."
- The report of Nicole Walsh that she experienced significant pain during the May 30, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Nicole Walsh from the May 30, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. Based on the available records, the 250 mg of fentanyl that was administered to Nicole Walsh on this date was adulterated by Nurse Monticone, who admitted to diverting 75% of all fentanyl stores at Yale between June 2020 and October 2020. Because an anesthesiologist did not participate in the procedure, it was the obligation of the administering nurse to examine the vial of fentanyl for visible signs of tampering, and if the vial exhibited evidence of tampering, to report signs of tampering to a supervisor and not administer the drug to the patient. Accordingly, if there was visible evidence that the fentanyl vial had been tampered with, then it was a deviation from the standard of care for Nurse Maureen Pothier to administer the adulterated fentanyl and to not report the incident to a supervisor.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Maureen Pothier and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

Since	ely,		

Dear Attorney Wisner,

Thank you for asking me to review the case of Dilay Nacar. This case involves the care that Dilay Nacar received at the Yale REI Clinic in Orange, CT for an October 4, 2020 egg retrieval surgery.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone admitted to adulterating at least 75% of all fentanyl administered at the clinic during a five month period, diluting or entirely replacing the fentanyl with saline (water). It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card,"
- The report of Dilay Nacar that she experienced significant pain during the October 4, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Dilay Nacar from the October 4, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. Based on the available records, the 250 mg of fentanyl that was administered to Dilay Nacar on this date was adulterated by Nurse Monticone, who admitted to diverting 75% of all fentanyl stores at Yale between June 2020 and October 2020. Because an anesthesiologist did not participate in the procedure, it was the obligation of the administering nurse to examine the vial of fentanyl for visible signs of tampering, and if the vial exhibited evidence of tampering, to report signs of tampering to a supervisor and not administer the drug to the patient. Accordingly, if there was visible evidence that the fentanyl vial had been tampered with, then it was a deviation from the standard of care for Nurse Donna Monticone to administer the adulterated fentanyl and to not report the incident to a supervisor.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Donna Monticone and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

Sincerely,						

Dear Attorney Wisner,

Thank you for asking me to review the case of Melissa Cowan. This case involves the care that Melissa Cowan received at the Yale REI Clinic in Orange, CT for an August 8, 2020 egg retrieval surgery.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone admitted to adulterating at least 75% of all fentanyl administered at the clinic during a five month period, diluting or entirely replacing the fentanyl with saline (water). It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card."
- The report of Melissa Cowan that she experienced significant pain during the August 8, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Melissa Cowan from the August 8, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. Based on the available records, the 150 mg of fentanyl that was administered to Melissa Cowan on this date was adulterated by Nurse Monticone, who admitted to diverting 75% of all fentanyl stores at Yale between June 2020 and October 2020. Because an anesthesiologist did not participate in the procedure, it was the obligation of the administering nurse to examine the vial of fentanyl for visible signs of tampering, and if the vial exhibited evidence of tampering, to report signs of tampering to a supervisor and not administer the drug to the patient. Accordingly, if there was visible evidence that the fentanyl vial had been tampered with, then it was a deviation from the standard of care for Nurse Jenna Barolli to administer the adulterated fentanyl and to not report the incident to a supervisor.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Jenna Barolli and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

Sincen	ary,		

Dear Attorney Wisner,

Thank you for asking me to review the case of Leah Mirakhor. This case involves the care that Leah Mirakhor received at the Yale REI Clinic in Orange, CT egg retrieval surgeries.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone replaced fentanyl with saline, knowing that saline (water) would be administered to patients instead of fentanyl, a potent analgesic. It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card." This document states that Nurse Monticone, in fact, admitted to tampering with 75% of all fentanyl administered at the clinic during a five month period. In other words, at least 75% of all fentanyl administered to REI Clinic patients during this period contained either no pain medication, or a subtherapeutic dose of pain medication.
- The report of Leah Mirakhor that she experienced significant pain during the July 1, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Leah Mirakhor from the September 8, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. These records indicate that Leah Mirakhor was treated at this clinic during the period when Nurse Monticone admitted to adulterating at least 75% of the clinic's fentanyl stores. These records also indicated that a total of 100 mg of fentanyl was administered to Leah Mirakhor on this date. While the records indicate that Anesthesiologist Jinlei Li, MD administered fentanyl on this date, because Nurse Monticone was present at the time of the procedure as reflected by the medical records the standard of care required Nurse Monticone to notify the patient about the adulterated fentanyl and/or prevent the administration of tampered fentanyl to the patient.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Monticone and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

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Dear Attorney Wisner,

Thank you for asking me to review the case of Awo Osafo-Addo. This case involves the care that Awo Osafo-Addo received at the Yale REI Clinic in Orange, CT for egg retrieval surgeries.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone replaced fentanyl with saline, knowing that saline (water) would be administered to patients instead of fentanyl, a potent analgesic. It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card." This document states that Nurse Monticone, in fact, admitted to tampering with 75% of all fentanyl administered at the clinic during a five month period. In other words, at least 75% of all fentanyl administered to REI Clinic patients during this period contained either no pain medication, or a subtherapeutic dose of pain medication.
- The report of Awo Osafo-Addo that she experienced significant pain during the September 18, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Awo Osafo-Addo from the June 26, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. These records indicate that Awo Osafo-Addo was treated at this clinic during the period when Nurse Monticone admitted to adulterating at least 75% of the clinic's fentanyl stores. These records also indicated that a total of 100 mg of fentanyl was administered to Awo Osafo-Addo on this date. While the records indicate that Anesthesiologist Jill Zafar, MD administered fentanyl on this date, because Nurse Monticone was present at the time of the procedure as reflected by the medical records the standard of care required Nurse Monticone to notify the patient about the adulterated fentanyl and/or prevent the administration of tampered fentanyl to the patient.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Monticone and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

Sincer	ely,		
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Dear Attorney Wisner,

Thank you for asking me to review the case of Alyssa Gargiulo. This case involves the care that Alyssa Gargiulo received at the Yale REI Clinic in Orange, CT for egg retrieval surgeries.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone replaced fentanyl with saline, knowing that saline (water) would be administered to patients instead of fentanyl, a potent analgesic. It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card." This document states that Nurse Monticone, in fact, admitted to tampering with 75% of all fentanyl administered at the clinic during a five month period. In other words, at least 75% of all fentanyl administered to REI Clinic patients during this period contained either no pain medication, or a subtherapeutic dose of pain medication.
- The report of Alyssa Gargiulo that she experienced significant pain during the August 24, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Alyssa Gargiulo from the August 5, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. These records indicate that Alyssa Gargiulo was treated at this clinic during the period when Nurse Monticone admitted to adulterating at least 75% of the clinic's fentanyl stores. These records also indicated that a total of 125 mg of fentanyl was administered to Alyssa Gargiulo on this date. While the records indicate that Anesthesiologist Alena S. Rady, DO administered fentanyl on this date, because Nurse Monticone was present at the time of the procedure as reflected by the medical records the standard of care required Nurse Monticone to notify the patient about the adulterated fentanyl and/or prevent the administration of tampered fentanyl to the patient.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Monticone and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

Sincerely,		

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Dear Attorney Wisner,

Thank you for asking me to review the case of Brianne McLoughlin. This case involves the care that Brianne McLoughlin received at the Yale REI Clinic in Orange, CT for egg retrieval surgeries.

As you know, I am trained and experienced in this same discipline (obstetric/gynecologic nursing), which resulted from my active involvement in the practice or teaching of nursing within the five-year period before the incident giving rise to this claim. As you are also aware, I am licensed to practice nursing in the State of Michigan, which you informed me requires the same or greater qualifications than the appropriate regulatory agency of the State of Connecticut.

As part of my prelitigation review of this matter, I relied on the following materials:

- The United States' May 18, 2021 Sentencing Memorandum. This Memorandum documented how Nurse Monticone replaced fentanyl with saline, knowing that saline (water) would be administered to patients instead of fentanyl, a potent analgesic. It additionally detailed how fentanyl stored at the Yale REI Clinic (Orange Location) was left unsecured so that "Ms. Monticone was able to access it at time without swiping her card." This document states that Nurse Monticone, in fact, admitted to tampering with 75% of all fentanyl administered at the clinic during a five month period. In other words, at least 75% of all fentanyl administered to REI Clinic patients during this period contained either no pain medication, or a subtherapeutic dose of pain medication.
- The report of Brianne McLoughlin that she experienced significant pain during the August 13, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT, despite documentation of receiving fentanyl for analgesia during the surgery.
- The medical records of Brianne McLoughlin from the May 29, 2020 egg retrieval surgery at the Yale REI Clinic in Orange, CT. These records indicate that Brianne McLoughlin was treated at this clinic during the period when Nurse Monticone admitted to adulterating at least 75% of the clinic's fentanyl stores. These records also indicated that a total of 75 mg of fentanyl was administered to Brianne McLoughlin on this date. While the records indicate that Anesthesiologist Jill Jafar, MD administered fentanyl on this date, because Nurse Monticone was present at the time of the procedure as reflected by the medical records the standard of care required Nurse Monticone to notify the patient about the adulterated fentanyl and/or prevent the administration of tampered fentanyl to the patient.

Accordingly, based on my review of the above, it is my opinion that there is evidence of medical negligence on the part of Nurse Monticone and/or her employer/principal. The opinion stated herein is based on the information available to me at this time. Should other information or evidence become available, I reserve the right to support and/or amend this opinion.

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EXHIBIT A

PETITION TO THE CLERK : SUPERIOR COURT

MELISSA COWAN AND : JUDICIAL DISTRICT ANY OTHER PLAINTIFFS : OF FAIRFIELD

YET TO BE IDENTIFIED

v. : AT BRIDGEPORT

YALE UNIVERSITY and/or their servants,
agents, apparent agents and/or employees
YALE SCHOOL OF MEDICINE and/or their
servants, agents, apparent agents and/or employees
YALE REPRODUCTIVE ENDOCRINOLOGY
AND INFERTILITY and/or their servants, agents,
apparent agents and/or employees
YALE NEW HAVEN HOSPITAL and/or their

YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees YALE NEW HAVEN HEALTH SERVICES : CORPORATION and/or their servants, agents, apparent agents and/or employees

YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents

and/or employees

YALE NEW HAVEN AMBULATORY
SERVICES CORPORATION and/or their
servants agent, apparent agents and/or employees

AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS.

AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED : APRIL 8, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to MELISSA COWAN to allow reasonable inquiry to determine that there was negligence in the care and treatment of MELISSA COWAN by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

JOSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE, NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

Asst. Clerk

Dated at <u>Bridgepert</u>, Connecticut, this <u>8th</u> day of April, 2021.

EXHIBIT B

PETITION TO THE CLERK : SUPERIOR COURT

ALYSSA GARGIULO AND : JUDICIAL DISTRICT ANY OTHER PLAINTIFFS : OF FAIRFIELD

YET TO BE IDENTIFIED

v. : AT BRIDGEPORT

YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents,

apparent agents and/or employees
YALE NEW HAVEN HOSPITAL and/or their
servants, agents, apparent agents and/or employees

YALE NEW HAVEN HEALTH SERVICES
CORPORATION and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN MEDICAL CENTER, INC.

and/or their servants, agents, apparent agents

and/or employees

YALE NEW HAVEN AMBULATORY
SERVICES CORPORATION and/or their
servants agent, apparent agents and/or employees
AND/OR ANY OTHER HEALTH CARE
PROVIDERS AND THEIR SERVANTS,

AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED : APRIL 8, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to ALYSSA GARGIULO to allow reasonable inquiry to determine that there was negligence in the care and treatment of ALYSSA GARGIULO by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

JOSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE. NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

Aush Clerk

Dated at 6 ndgeper, Connecticut, this 8 day of April, 2021.

EXHIBIT C

PETITION TO THE CLERK : SUPERIOR COURT

BRIANNE MCLOUGHLIN AND : JUDICIAL DISTRICT

ANY OTHER PLAINTIFFS : OF FAIRFIELD

YET TO BE IDENTIFIED

v. : AT BRIDGEPORT

YALE UNIVERSITY and/or their servants, :

agents, apparent agents and/or employees

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees

YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN HOSPITAL and/or their

servants, agents, apparent agents and/or employees
YALE NEW HAVEN HEALTH SERVICES:

CORPORATION and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN MEDICAL CENTER, INC.

and/or their servants, agents, apparent agents

and/or employees

YALE NEW HAVEN AMBULATORY

SERVICES CORPORATION and/or their

servants agent, apparent agents and/or employees

AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS.

AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED

APRIL 14, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to BRIANNE MCLOUGHLIN to allow reasonable inquiry to determine that there was negligence in the care and treatment of BRIANNE MCLOUGHLIN by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

VOSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE. NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

Ast Clerk

Dated at Bridgeport, Connecticut, this 14th day of April, 2021.



PETITION TO THE CLERK SUPERIOR COURT

LEAH MIRAKHOR AND JUDICIAL DISTRICT

ANY OTHER PLAINTIFFS OF FAIRFIELD YET TO BE IDENTIFIED

v. AT BRIDGEPORT

YALE UNIVERSITY and/or their servants,

agents, apparent agents and/or employees

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees YALE REPRODUCTIVE ENDOCRINOLOGY

AND INFERTILITY and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees

YALE NEW HAVEN HEALTH SERVICES

CORPORATION and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN MEDICAL CENTER, INC.

and/or their servants, agents, apparent agents

and/or employees

YALE NEW HAVEN AMBULATORY

SERVICES CORPORATION and/or their

servants agent, apparent agents and/or employees

AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS.

AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED

APRIL 28, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to LEAH MIRAKHOR to allow reasonable inquiry to determine that there was negligence in the care and treatment of LEAH MIRAKHOR by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

JOSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE. NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

The Zimi

Clerk

Dated at $\frac{\beta_r \mathcal{A}_{2c_r-c_r+}}{\beta_r}$, Connecticut, this $\frac{2\beta^r}{\beta_r}$ day of April, 2021.



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PETITION TO THE CLERK : SUPERIOR COURT

DILAY NACAR AND : JUDICIAL DISTRICT

ANY OTHER PLAINTIFFS : OF FAIRFIELD YET TO BE IDENTIFIED

v. : AT BRIDGEPORT

YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees

YALE SCHOOL OF MEDICINE and/or their

servants, agents, apparent agents and/or employees

YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents,

apparent agents and/or employees

VALE MENT HAVEN HOSDITAL and/on

YALE NEW HAVEN HOSPITAL and/or their

servants, agents, apparent agents and/or employees

YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN MEDICAL CENTER, INC.

and/or their servants, agents, apparent agents

and/or employees

YALE NEW HAVEN AMBULATORY

SERVICES CORPORATION and/or their

servants agent, apparent agents and/or employees

AND/OR ANY OTHER HEALTH CARE

PROVIDERS AND THEIR SERVANTS,

AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED : JUNE 11, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to DILAY NACAR to allow reasonable inquiry to determine that there was negligence in the care and treatment of DILAY NACAR by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

JOSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE. NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

Aut. Clerk

Dated at Brid gapart, Connecticut, this 11th day of June, 2021.



PETITION TO THE CLERK : SUPERIOR COURT

AWO OSAFO-ADDO AND : JUDICIAL DISTRICT ANY OTHER PLAINTIFFS : OF FAIRFIELD

YET TO BE IDENTIFIED

v. : AT BRIDGEPORT

YALE UNIVERSITY and/or their servants, :

agents, apparent agents and/or employees

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees

YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN HOSPITAL and/or their

servants, agents, apparent agents and/or employees
YALE NEW HAVEN HEALTH SERVICES

CORPORATION and/or their servants, agents,

apparent agents and/or employees

YALE NEW HAVEN MEDICAL CENTER, INC. :

and/or their servants, agents, apparent agents

and/or employees

YALE NEW HAVEN AMBULATORY :

SERVICES CORPORATION and/or their

servants agent, apparent agents and/or employees

AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS,

AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED : APRIL 14, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to AWO OSAFO-ADDO to allow reasonable inquiry to determine that there was negligence in the care and treatment of AWO OSAFO-ADDO by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

JOSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE. NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

Asst Clerk

Dated at Bridgert, Connecticut, this 14th day of April, 2021.

EXHIBIT G

PETITION TO THE CLERK : SUPERIOR COURT

NICOLE WALSH AND : JUDICIAL DISTRICT
ANY OTHER PLAINTIFFS : OF FAIRFIELD
YET TO BE IDENTIFIED

v. : AT BRIDGEPORT

YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees
YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees
YALE REPRODUCTIVE ENDOCRINOLOGY
AND INFERTILITY and/or their servants, agents, apparent agents and/or employees
YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees
YALE NEW HAVEN HEALTH SERVICES
CORPORATION and/or their servants, agents, apparent agents and/or employees
YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees
YALE NEW HAVEN AMBULATORY

YALE NEW HAVEN AMBULATORY
SERVICES CORPORATION and/or their
servants agent, apparent agents and/or employees
AND/OR ANY OTHER HEALTH CARE
PROVIDERS AND THEIR SERVANTS,
AGENTS AND/OR EMPLOYEES

AS YET TO BE DETERMINED : APRIL 8, 2021

Pursuant to Connecticut General Statutes Section 52-190a(b), the undersigned hereby petitions for the AUTOMATIC ninety (90) day extension of the Statute of Limitations which has not run as yet regarding the course of treatment given to **NICOLE WALSH** to allow reasonable inquiry to determine that there was negligence in the care and treatment of **NICOLE WALSH** by YALE UNIVERSITY and/or their servants, agents, apparent agents and/or employees;

YALE SCHOOL OF MEDICINE and/or their servants, agents, apparent agents and/or employees; YALE REPRODUCTIVE ENDOCRINOLOGY AND INFERTHLITY and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HOSPITAL and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN HEALTH SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN MEDICAL CENTER, INC. and/or their servants, agents, apparent agents and/or employees; YALE NEW HAVEN AMBULATORY SERVICES CORPORATION and/or their servants, agents, apparent agents and/or employees; AND/OR ANY OTHER HEALTH CARE PROVIDERS AND THEIR SERVANTS, AGENTS AND/OR EMPLOYEES AS YET TO BE DETERMINED.

COUNSEL FOR THE PETITIONER.

OSH KOSKOFF, ESQ.

KOSKOFF, KOSKOFF & BIEDER, P.C.

350 FAIRFIELD AVENUE

BRIDGEPORT, CONNECTICUT 06604

JURIS NO.: 410518

TELE, NO. 203-336-4421

ORDER

The foregoing Petition having been presented to the Clerk of the Court pursuant to Connecticut General Statutes § 52-190a (b), it is hereby ordered that the statute of limitations be extended for ninety (90) days.

BY THE COURT

Asst. Clerk

Dated at _______, Connecticut, this _______ day of April, 2021.